NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
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1985

FEDERAL REGISTER

Vol. 81 Wednesday,
No. 96 May 18, 2016

Pages 31161–31488

OFFICE OF THE FEDERAL REGISTER

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Title 3—

The President

Memorandum of May 10, 2016

Delegation of Authority Pursuant to Section 3136(h) of the National Defense Authorization Act for Fiscal Year 2016

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby order as follows:

I hereby delegate functions and authorities vested in the President by section 3136(h) of the National Defense Authorization Act for Fiscal Year 2016 (Public Law 114–92) (the "Act") to the Secretary of State.

Any reference in this memorandum to the Act shall be deemed to be a reference to any future act that is the same or substantially the same as such provision.

You are authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
Washington, May 10, 2016

[FR Doc. 2016–11836
Filed 5–17–16; 8:45 am]
Billing code 4710–10–P

Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Rural Housing Service

7 CFR Part 3555

RIN 0575–AD04

Single Family Housing Guaranteed Loan Program

AGENCY: Rural Housing Service, USDA.

ACTION: Final rule.

SUMMARY: The Rural Housing Service (RHS or Agency) is amending the current regulation for the Single Family Housing Guaranteed Loan Program (SFHGLP) on the subject of liquidation value appraisals. In order to reduce overall processing time, reduce cost, and expedite claim submission, lenders will order the liquidation value appraisal used to estimate a loss claim against the SFHGLP instead of the Agency. Currently, if a Real Estate Owned (REO) property remains unsold by the lender at the end of the permissible marketing period, the Agency orders a liquidation value appraisal and applies an acquisition and management resale factor to estimate holding and disposition cost. This amendment requires the servicing lender to order the liquidation value appraisal. The costs associated with obtaining the liquidation value appraisal can then be included in the liquidation costs paid under the guarantee.

DATES: *Effective Date:* June 17, 2016.

FOR FURTHER INFORMATION CONTACT: Lilian Lipton, Finance and Loan Analyst, Single Family Housing Guaranteed Loan Division, STOP 0784, Room 2250, USDA Rural Development, South Agriculture Building, 1400 Independence Avenue SW., Washington, DC 20250–0784, telephone: (202) 260–8012, email is *lilian.lipton@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION: RHS amends the current regulation for the Single Family Housing Guaranteed Loan Program (SFHGLP) on the subject of liquidation value appraisals. In order to reduce overall processing time, reduce cost, and expedite claim submission, lenders will order the liquidation value appraisal used to estimate a loss claim against the SFHGLP instead of the Agency. Specifically, RHS amends 7 CFR 3555.306(f)(3), 3555.352(e), 3555.353(b)(1), and 3555.354(b)(1)(i) and (ii) and (b)(2).

Executive Order 12866, Classification

This rule has been determined to be non-significant and, therefore was not reviewed by the Office of Management and Budget (OMB) under Executive Order 12866.

Executive Order 12988, Civil Justice Reform

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Except where specified, all State and local laws and regulations that are in direct conflict with this rule will be preempted. Federal funds carry Federal requirements. No person is required to apply for funding under SFHGLP, but if they do apply and are selected for funding, they must comply with the requirements applicable to the Federal program funds. This final rule is not retroactive. It will not affect agreements entered into prior to the effective date of the rule. Before any judicial action may be brought regarding the provisions of this rule, the administrative appeal provisions of 7 CFR part 11 must be exhausted.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effect of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, the Agency generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, or tribal governments, in the aggregate, or to the private sector, of $100 million, or more, in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires the Agency to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule.

This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, and tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR part 1940, subpart G, "Environmental Program." It is the determination of the Agency that this action does not constitute a major Federal action significantly affecting the quality of the human environment, and, in accordance with the National Environmental Policy Act of 1969, Public Law 91–190, neither an Environmental Assessment nor an Environmental Impact Statement is required.

Executive Order 13132, Federalism

The policies contained in this rule do not have any substantial direct effect on States, on the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Nor does this rule impose substantial direct compliance costs on State and local governments. Therefore, consultation with the States is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) the undersigned has determined and certified by signature of this document that this rule change will not have a significant impact on a substantial number of small entities. This rule does not impose any significant new requirements on Agency applicants and borrowers, and the regulatory changes affect only Agency determination of program benefits for guarantees of loans made to individuals.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 imposes requirements on RHS in the development of regulatory policies that have Tribal implications or preempt tribal laws. RHS has determined that the rule does not have a substantial direct effect on one or more Indian Tribe(s) or on either the relationship or the distribution of powers and responsibilities between the Federal Government and Indian Tribes. Thus, this final rule is not subject to the requirements of Executive Order 13175. If a Tribe determines that this rule has implications of which RHS is not aware and would like to engage with RHS on this rule, please contact USDA Rural Development's Native American Coordinator at (720) 544–2911 or *AIAN@wdc.usda.gov.*

Executive Order 12372, Intergovernmental Consultation

These loans are subject to the provisions of Executive Order 12372, which require intergovernmental consultation with State and local officials. RHS conducts intergovernmental consultations for each SFHGLP in accordance with 2 CFR part 415, subpart C.

Programs Affected

The program affected by this regulation is listed in the Catalog of Federal Domestic Assistance under Number 10.410, Very Low to Moderate Income Housing Loans (Section 502 Rural Housing Loans).

Paperwork Reduction Act

The information collection and record keeping requirements contained in this regulation have been approved by OMB in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The assigned OMB control number is 0570–0179.

E-Government Act Compliance

The Agency is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Non-Discrimination Policy

The U.S. Department of Agriculture (USDA) prohibits discrimination against its customers, employees, and applicants for employment on the bases of race, color, national origin, age, disability, sex, gender identity, religion, reprisal, and where applicable, political beliefs, marital status, familial or parental status, sexual orientation, or all or part of an individual's income is derived from any public assistance program, or protected genetic information in employment or in any program or activity conducted or funded by the Department. (Not all prohibited bases will apply to all programs and/or employment activities.)

If you wish to file a Civil Rights program complaint of discrimination, complete the USDA Program Discrimination Complaint Form (PDF), found online at *http://www.ascr.usda.gov/complaint_filing_cust.html,* or at any USDA office, or call (866) 632–9992 to request the form. You may also write a letter containing all of the information requested in the form. Send your completed complaint form or letter to us by mail at U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410, by fax (202) 690–7442 or email at *program.intake@usda.gov.*

Individuals who are deaf, hard of hearing or have speech disabilities and you wish to file either an EEO or program complaint please contact USDA through the Federal Relay Service at (800) 877–8339 or (800) 845–6136 (in Spanish).

Persons with disabilities, who wish to file a program complaint, please see information above on how to contact us by mail directly or by email. If you require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, etc.) please contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

I. Background Information

On October 6, 2015, RHS published a proposed rule with request for comments for the Single Family Housing Guaranteed Loan Program (SFHGLP) (80 FR 60298–60300). Rural Development received comments from one respondent. The comments are addressed below.

II. Discussion of the Comments Received

Comment: The respondent strongly supported the Agency's proposal and requested clarification: (1) If mortgagees will be required to order a liquidation value appraisal when a sale date for a possessed home has been scheduled, but the sale date falls outside the permissible marketing period; (2) if mortgagees should order a liquidation value appraisal for the property when a contract for a sale falls through after the permissible marketing period has expired; and (3) if mortgagees will be held liable for not having ordered a liquidation value appraisal in the event a home sale is scheduled to be finalized on a date that is near the end of the permissible marketing period and the sale falls through.

RHS response: Technical details of lenders responsibilities while servicing non-performing loans are explained in the Agency's 3555 Handbook, therefore there will be no changes made in this provision.

List of Subjects in 7 CFR Part 3555

Home improvement, Loan programs—housing and community development, Mortgage insurance, Mortgages, Rural areas.

Therefore, chapter XXXV, title 7 of the Code of Federal Regulations is amended as follows:

PART 3555—GUARANTEED RURAL HOUSING PROGRAM

■ 1. The authority citation for part 3555 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 1471 *et seq.*

Subpart G—Servicing Non-Performing Loans

■ 2. Section 3555.306 is amended by revising paragraph (f)(3) to read as follows:

§ 3555.306 Liquidation.

* * * * *

(f) * * *

(3) The lender must notify the Agency when the property has not been sold within 30 days of the expiration of the permissible marketing period. If the REO remains unsold at the end of the permissible marketing period, the lender will order a liquidation value appraisal and the Agency will apply an acquisition and management resale factor to estimate holding and disposition cost. Interest expenses accrued beyond 90 days of the foreclosure sale date or expiration of any redemption period, whichever is later, will be the responsibility of the lender and not covered by the guarantee.

* * * * *

Subpart H—Collecting on the Guarantee

■ 3. Section 3555.352 is amended by revising paragraph (e) to read as follows:

§ 3555.352 Loss covered by the guarantee.

* * * * *

(e) *Liquidation costs.* Reasonable and customary liquidation costs, such as attorney fees, liquidation value appraisals, and foreclosure costs. Annual fees advanced by the lender to the Agency are ineligible for reimbursement when calculating the loss payment, as otherwise provided by the Agency.

■ 4. Section 3555.353 is amended by revising paragraph (b)(1) to read as follows:

§ 3555.353 Net recovery value.

* * * * *

(b) * * *

(1) The value of the property as determined by a liquidation value appraisal. The value should be determined as if the property would be sold without the market exposure it would ordinarily receive in a normal transaction, or within 90 days, minus;

* * * * *

■ 5. Section 3555.354 is amended by revising paragraphs (b)(1) and (2) to read as follows:

§ 3555.354 Loss claim procedures.

* * * * *

(b) * * *

(1) The lender must submit a loss claim request that includes a completed liquidation value appraisal within 30 calendar days of the period ending:

(i) Nine (9) months after either foreclosure or the end of any applicable redemption period, whichever is later, if the property remains unsold and is not located on American Indian restricted land; or

(ii) Twelve (12) months after either foreclosure or the end of any applicable redemption period, whichever is later, if the property remains unsold and is located on American Indian restricted land. Late claims made beyond this period of time, or submitted with a liquidation value appraisal not completed within the timeframes described in paragraphs (b)(1)(i) and (ii) of this section, may be rejected.

(2) The lender must submit a loss claim that includes the completed liquidation value appraisal within 30 calendar days of receiving the appraisal. Late claims made beyond this period of time, or submitted with a liquidation value appraisal not completed within the timeframes described in paragraphs (b)(1)(i) and (ii) of this section, may be rejected.

* * * * *

Dated: March 26, 2016.

Tony Hernandez,

Administrator, Rural Housing Service.

[FR Doc. 2016–11608 Filed 5–17–16; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9769]

RIN 1545–BK08

Removal of Allocation Rule for Disbursements From Designated Roth Accounts to Multiple Destinations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations eliminating the requirement that each disbursement from a designated Roth account that is directly rolled over to an eligible retirement plan be treated as a separate distribution from any amount paid directly to the employee and therefore separately subject to the rule in section 72(e)(2) of the Internal Revenue Code (the Code) allocating pretax and after-tax amounts to each distribution. As a result of this change, if disbursements are made from a taxpayer's designated Roth account to the taxpayer and also to the taxpayer's Roth IRA or designated Roth account in a direct rollover, then pretax amounts will be allocated first to the direct rollover, rather than being allocated pro rata to each destination. Also, a taxpayer will be able to direct the allocation of pretax and after-tax amounts that are included in disbursements from a designated Roth account that are directly rolled over to multiple destinations, applying the same allocation rules to distributions from designated Roth accounts that apply to distributions from other types of accounts. These regulations affect participants in, beneficiaries of, employers maintaining, and administrators of designated Roth accounts under tax-favored retirement plans.

DATES: *Effective Date:* These regulations are effective on May 18, 2016.

Applicability Date: These regulations generally apply to distributions on or after January 1, 2016 (or an earlier date chosen by the taxpayer that is on or after September 18, 2014). For more information see the "Effective/Applicability Dates" section of this preamble.

FOR FURTHER INFORMATION CONTACT: Michael Brewer at (202) 317–6700 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 402(a) provides generally that any amount distributed from a trust described in section 401(a) that is exempt from tax under section 501(a) is taxable to the distributee under section 72 in the taxable year of the distributee in which distributed. Under section 403(b)(1), any amount distributed from a section 403(b) plan is also taxable to the distributee under section 72.

If a participant's account balance in a plan qualified under section 401(a) or in a section 403(b) plan includes both after-tax and pretax amounts, then, under section 72(e)(8), each distribution (other than a distribution that is paid as part of an annuity) from the plan will include a pro rata share of both after-tax and pretax amounts. (Under section 72(d), a different allocation method applies to annuity distributions.)

Section 402(c) prescribes rules for amounts that are rolled over from qualified trusts to eligible retirement plans, including individual retirement accounts or annuities ("IRAs"). Subject to certain exceptions, section 402(c)(1) provides that if any portion of an eligible rollover distribution paid to an employee from a qualified trust is transferred to an eligible retirement plan, the portion of the distribution so transferred is not includible in gross income in the taxable year in which paid.

Under section 402(c)(2), the maximum portion of an eligible rollover distribution that may be rolled over in a transfer to which section 402(c)(1) applies generally cannot exceed the portion of the distribution that is otherwise includible in gross income. However, under section 402(c)(2)(A) and (B), the general rule does not apply to such a distribution to the extent that such portion is transferred in a direct trustee-to-trustee transfer to a qualified trust or to an annuity contract described in section 403(b) and such trust or contract provides for separate accounting for amounts so transferred (and earnings thereon), including separately accounting for the portion of such distribution which is includible in gross income and the portion of such distribution which is not so includible, or such portion is transferred to an IRA.

In addition, section 402(c)(2) provides that, in the case of a transfer described in subparagraph (A) or (B), the amount transferred shall be treated as consisting first of the portion of such distribution that is includible in gross income (determined without regard to section 402(c)(1)).

Under section 402A, an applicable retirement plan may include a designated Roth account. An applicable retirement plan is defined in section 402A(e)(1) to mean a plan qualified under section 401(a), a section 403(b) plan, and a governmental section 457(b) plan. Section 402A(d) provides that a qualified distribution (as defined in section 402A(d)(2)) from a designated Roth account is not includible in gross income.

Under section 402A(d)(4), section 72 is applied separately with respect to distributions and payments from a designated Roth account and other distributions and payments from the plan.

Section 1.402A–1, Q&A–5(a), of the Income Tax Regulations prescribes taxability rules for a distribution from a designated Roth account that is rolled over. Q&A–5(a) provides, in part, that "any amount paid in a direct rollover is treated as a separate distribution from any amount paid directly to the employee" (the "separate distribution rule").

Proposed regulations limiting the applicability of the separate distribution rule of § 1.402A–1, Q&A–5(a), were published on September 19, 2014 (REG–105739–11, 79 FR 56310). The proposed regulations achieved this result by adding, after the separate distribution rule in paragraph A–5(a), the following sentence: "The preceding sentence does not apply to distributions made on or after January 1, 2015; in addition, a taxpayer may elect not to apply the preceding sentence to distributions made on or after an earlier date that is no earlier than September 18, 2014." Thus, under the proposed regulations, an amount paid in a direct rollover is not required to be treated as a separate distribution from any amount paid directly to the employee.

The proposed regulations were issued in conjunction with Notice 2014–54 (2014–41 IRB 670 (October 6, 2014)), which specified that a taxpayer may direct after-tax and pretax amounts that are simultaneously disbursed to multiple destinations so as to allocate them to specific destinations. Under Notice 2014–54, a taxpayer may direct the allocation of after-tax and pretax amounts in connection with disbursements that are directly rolled over, as well as in connection with disbursements that are rolled over in 60-day rollovers.

No comments were received regarding the proposed regulations.

Explanation of Provisions

These regulations finalize the proposed regulations, with a 1-year delay of the applicability date (from January 1, 2015, to January 1, 2016). They are substantively the same as the proposed regulations, but express the rule differently to better reflect the ongoing rule and the transition rule. For distributions made on or after January 1, 2016, the final regulations remove the sentence in the existing regulations that provided the separate distribution rule. For earlier distributions, the final regulations add a sentence at the end of the paragraph which provides that a separate distribution rule applies to distributions made prior to January 1, 2016, unless a taxpayer elects not to apply that rule with respect to a distribution made on or after September 18, 2014.

Effective/Applicability Dates

These regulations apply to distributions from designated Roth accounts made on or after January 1, 2016, and for such distributions taxpayers are required to follow the allocation rules described in Notice 2014–54.

These regulations also preserve the separate distribution rule for distributions made prior to the January 1, 2016, applicability date, except that a taxpayer is permitted to choose not to apply the separate distribution rule to distributions that are made on or after September 18, 2014, and before January 1, 2016. Taxpayers choosing not to apply the separate distribution rule to distributions made during that transition period, must apply a reasonable interpretation of the last sentence of section 402(c)(2) (generally requiring that pretax amounts be treated as rolled over first) to allocate pretax and after-tax amounts among disbursements made to multiple destinations. For this purpose, a reasonable interpretation of the last sentence of section 402(c)(2) includes the rules described in Notice 2014–54.

Statement of Availability of IRS Documents

Notice 2014–54 is published in the Internal Revenue Bulletin and is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, or by visiting the IRS Web site at *http://www.irs.gov.*

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply.

Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Michael Brewer, Office of the IRS Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and the Department of Treasury participated in the development of the regulations.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.402A–1 is amended by removing the third sentence of paragraph A–5(a) and adding a new sentence to the end of paragraph A–5(a) to read as follows:

§ 1.402A–1 Designated Roth Accounts.

* * * * *

A–5. (a) * * * For distributions made prior to January 1, 2016, any amount paid in a direct rollover is treated as a separate distribution from any amount paid directly to the employee, except that taxpayers may choose not to apply this sentence to distributions made on or after September 18, 2014, and before January 1, 2016.

* * * * *

John M. Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: March 24, 2016.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2016–11647 Filed 5–17–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

[Docket No. OSHA–2010–0034]

RIN 1218–AB70

Occupational Exposure to Respirable Crystalline Silica

Correction

In rule document 2016–04800 appearing on pages 16285–16890 in the issue of March 25, 2016, make the following corrections:

§ 1910.1000 [Corrected]

■ (1) On pages 16861–16862, in § 1910.100, Table Z–3—Mineral Dusts is corrected to read as set forth below:

TABLE Z-3–MINERAL DUSTS

Substance	mppcf[a]	mg/m³
Silica		
Crystalline		
Quartz (Respirable)[f]	$\frac{250^{b}}{\%SiO_2+5}$	$\frac{10\ mg/m^{3\ e}}{\%\ SiO_2+2}$
Cristobalite: Use ½ the value calculated from the count or mass formulae for quartz[f]		
Tridymite: Use ½ the value calculated from the formulae for quartz[f]		

* * * * * * *

* * * * *

§ 1915.1000 [Corrected]

■ (2) On page 16875, in § 1910.100, Table Z—Shipyards is corrected to read as set forth below:

TABLE Z – SHIPYARDS

Substance	CAS No.[d]	ppm [a*]	mg/m^{3} [b*]	Skin designation
* * * * * * *				
Silica, crystalline, respirable dust				
Cristobalite; see 1915.1053	14464-46-1			
Quartz; see 1915.1053[5]	14808-60-7			
Tripoli (as quartz); see 1915.1053[5]	1317-95-9			
Trydimite; see 1915.1053	15468-32-3			
* * * * * * *				

MINERAL DUSTS

Substance	mppcf (j)
SILICA:	
Crystalline	
Quartz. Threshold Limit calculated from the formula (p).........	$\frac{250^{(k)}}{\% SiO^{2}+5}$
* * * * * * *	

* * * * *

§ 1926.55 [Corrected]

■ (3) On pages 16875–16876, in § 1926.55, the table titled “Threshold Limit Values of Airborne Contaminants for Construction” is corrected to read as set forth below:

THRESHOLD LIMIT VALUES OF AIRBORNE CONTAMINANTS FOR CONSTRUCTION

Substance	CAS No.^{d}	ppm ^{a*}	mg/m$^{3\ b}$	Skin designation
* *	*	*	*	* *
Silica, crystalline, respirable dust				
Cristobalite; see 1926.1153	14464-46-1			
Quartz; see 1926.1153^{5}	14808-60-7			
Tripoli (as quartz); see 1926.1153^{5}	1317-95-9			
Trydimite; see 1926.1153	15468-32-3			
* *	*	*	*	* *

MINERAL DUSTS

SILICA:	
Crystalline	
Quartz. Threshold Limit calculated from the formula $^{(p)}$………	$\frac{250^{(k)}}{\%\ SiO2+5}$
* * * * *	* *

* * * * *

[FR Doc. C1–2016–04800 Filed 5–17–16; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 537

Burmese Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is amending the Burmese Sanctions Regulations to add a general license authorizing certain transactions related to U.S. persons residing in Burma. OFAC is also incorporating a general license authorizing certain transactions incident to exports to and from Burma that has, until now, appeared only on OFAC's Web site on the Burma sanctions page, and expanding this authorization to allow certain transactions incident to the movement of goods within Burma that otherwise would be prohibited. Finally, OFAC is expanding and updating another existing authorization allowing most transactions involving certain blocked financial institutions.

DATES: *Effective:* May 18, 2016.

FOR FURTHER INFORMATION CONTACT: The Department of the Treasury's Office of Foreign Assets Control: Assistant Director for Licensing, tel.: 202–622–2480, Assistant Director for Regulatory Affairs, tel.: 202–622–4855, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; or the Department of the Treasury's Office of the Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*www.treasury.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs also is available via facsimile through a 24-hour fax-on-demand service, tel.: 202–622–0077.

Background

On June 30, 2014, the Department of the Treasury's Office of Foreign Assets Control (OFAC) amended and reissued in their entirety the Burmese Sanctions Regulations, 31 CFR part 537 (the "Regulations"), to implement Executive Order 13448 of October 18, 2007, "Blocking Property and Prohibiting Certain Transactions Related to Burma," Executive Order 13464 of April 30, 2008, "Blocking Property and Prohibiting Certain Transactions Related to Burma," Executive Order 13619 of July 11, 2012, "Blocking Property of Persons Threatening the Peace, Security, or Stability of Burma," and Executive Order 13651 of August 6, 2013, "Prohibiting Certain Imports of Burmese Jadeite and Rubies" (79 FR 37106).

Following Burma's peaceful and competitive elections in 2015, the U.S. Government is taking additional steps to support Burma's political reforms and broad-based economic growth.

Transactions related to U.S. persons residing in Burma. OFAC is adding a general license in section 537.525 to authorize certain transactions related to maintenance of U.S. persons residing in Burma, including payment of living expenses and acquisition of goods or services for personal use. This general license complements the existing exemption in section 537.210(c) of the Regulations for travel to or from Burma, including maintenance within Burma, such as payment of living expenses and acquisition of goods or services for personal use.

Trade-related transactions. In December 2015, OFAC issued and made available on its Web site General License No. 20, a six-month general license authorizing certain transactions ordinarily incident to exportations to or from Burma of goods, technology, or non-financial services that are otherwise prohibited by the Regulations and unblocking certain previously blocked transactions. Today, OFAC is amending the Regulations by adding section 537.532 to incorporate that general license, to remove its six-month time limitation, and to expand this authorization to allow additional transactions incident to the movement of goods within Burma.

Banking services. In February 2013, OFAC issued and made available on its Web site General License No. 19, and subsequently added this authorization to the Regulations at section 537.531, authorizing most transactions, including opening and maintaining accounts and conducting other financial services, involving four of Burma's major financial institutions that were then included on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List): Asia Green Development Bank, Ayeyarwady Bank, Myanma Economic Bank (MEB), and Myanma Investment and Commercial Bank (MICB). In an action coordinated with these regulatory amendments, OFAC has delisted two of these financial institutions, MEB and MICB. As a result of that action, transactions involving these two institutions are no longer prohibited and therefore do not require an OFAC license. Accordingly, OFAC is amending section 537.531 to remove their names. At the same time, to further support Burma's broad-based economic growth, OFAC is adding two other Burmese financial institutions, Innwa Bank and Myawaddy Bank, to the general license at section 537.531, thereby authorizing most transactions involving those institutions.

Public Participation

Because the Regulations involve a foreign affairs function, the provisions of Executive Order 12866 and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to the Regulations are contained in 31 CFR part 501 (the "Reporting, Procedures and Penalties Regulations"). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

List of Subjects in 31 CFR Part 537

Administrative practice and procedure, Banks, Banking, Blocking of assets, Credit, Burma, Exportation, Exports, Foreign trade, Investments, Loans, New investment, Securities, Services, Specially Designated Nationals.

For the reasons set forth in the preamble, the Department of the Treasury's Office of Foreign Assets Control amends 31 CFR part 537 as set forth below:

PART 537—BURMESE SANCTIONS REGULATIONS

■ 1. The authority citation for part 537 is revised to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Sec. 570, Pub. L. 104–208, 110 Stat. 3009; Pub. L. 110–96, 121 Stat. 1011 (50 U.S.C. 1701 note); Pub. L. 110–286, 122 Stat. 2632 (50 U.S.C. 1701 note); E.O. 13047, 62 FR 28301, 3 CFR, 1997 Comp., p. 202; E.O. 13310, 68 FR 44853, 3 CFR, 2003 Comp., p. 241; E.O. 13448, 72 FR 60223, 3 CFR, 2007 Comp., p. 304; E.O. 13464, 73 FR 24491, 3 CFR, 2008 Comp., p. 189; E.O. 13619, 77 FR 41243, 3 CFR, 2012 Comp., p. 279; E.O. 13651, 78 FR 48793, 3 CFR, 2014 Comp., p. 324; Determination No. 2009–11, 74 FR 3957, 3 CFR, 2009 Comp., p. 330.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 2. Add § 537.525 to read as follows:

§ 537.525 Certain transactions related to U.S. persons residing in Burma authorized.

(a) U.S. persons are authorized to engage in transactions in Burma ordinarily incident to the routine and necessary maintenance within Burma, including payment of living expenses and acquisition of goods or services for personal use, of U.S. person individuals who reside in Burma.

(b) Nothing in this section authorizes transactions related to employment of a U.S. person by a person whose property and interests in property are blocked pursuant to § 537.201(a).

Note to § 537.525: See § 537.210(c) for an exemption for transactions ordinarily incident to travel to or from Burma, including maintenance within Burma, such as payment of living expenses and acquisition of goods or services for personal use.

■ 3. Amend § 537.531 by revising the section heading, revising paragraphs (a), (b), and (d), and revising the Note to § 537.531 to read as follows:

§ 537.531 Certain transactions involving Asia Green Development Bank, Ayeyarwady Bank, Innwa Bank, and Myawaddy Bank authorized.

(a) Except as provided in paragraphs (b) through (f) of this section, all transactions involving Asia Green Development Bank, Ayeyarwady Bank, Innwa Bank, and Myawaddy Bank are authorized.

(b) This section does not authorize transactions involving any person whose property and interests in property are blocked pursuant to § 537.201(a) other than Asia Green Development Bank, Ayeyarwady Bank, Innwa Bank, and Myawaddy Bank.

* * * * *

(d) This section does not authorize any new investment, as defined in § 537.311, including in or with Asia Green Development Bank, Ayeyarwady Bank, Innwa Bank, or Myawaddy Bank.

* * * * *

Note to § 537.531: As a result of the authorization contained in this section, the special measures against Burma imposed under Section 311 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001 (Pub. L. 107–56) (USA PATRIOT Act) do not apply to the operation of correspondent accounts for Asia Green Development Bank, Ayeyarwady Bank, Innwa Bank, and Myawaddy Bank, or to transactions conducted through such accounts, provided the transactions are authorized pursuant to this part, and therefore fall within the exception set forth in 31 CFR 1010.651(b)(3). This section does not affect any obligation of U.S. financial institutions processing such transactions to conduct enhanced due diligence under Section 312 of the USA PATRIOT Act. *See* 31 CFR 1010.610(c).

■ 4. Add § 537.532 to subpart E to read as follows:

§ 537.532 Certain transactions incident to exportations to or from Burma authorized; certain transactions incident to the movement of goods within Burma authorized.

(a) *Certain transactions incident to exportations to or from Burma authorized.* Except as provided in paragraph (c), all transactions otherwise prohibited by §§ 537.201 and 537.202 that are ordinarily incident to an exportation to or from Burma of goods, technology, or non-financial services, as defined in paragraph (f) of this section, are authorized, provided the exportation is not to, from, or on behalf of a person whose property and interests in property are blocked pursuant to § 537.201(a).

(b) *Unblocking of certain property previously blocked as part of a transaction incident to an exportation to or from Burma authorized.* U.S. financial institutions, as defined in § 537.320, are authorized to engage in all transactions necessary to unblock and return property blocked as part of a transaction on or after April 1, 2015 that would have qualified as authorized had it been engaged in under paragraph (a) of this section. U.S. financial institutions unblocking property pursuant to this section must submit a report to the Department of the Treasury, Office of Foreign Assets Control, Attn: Sanctions Compliance & Evaluation Division, 1500 Pennsylvania Avenue NW., Annex, Washington, DC 20220 within 10 business days from the date such property is unblocked. Such reports shall include the following:

(1) A copy of the original blocking report filed with OFAC pursuant to § 501.603(b)(1) of this chapter;

(2) The date the property was unblocked;

(3) If applicable, the amount unblocked;

(4) The name of the party to whom the blocked property was returned; and

(5) A reference to this general license as the legal authority under which the property was unblocked and the blocked property was returned.

(c) Paragraphs (a) and (b) of this section do not authorize:

(1) The unblocking of any property or interests in property that were blocked pursuant to § 537.201(a) prior to April 1, 2015.

(2) A U.S. financial institution to advise or confirm any financing by a person whose property and interests in property are blocked pursuant to § 537.201(a).

(d) *Certain transactions incident to the movement of goods within Burma authorized.* Except as provided in paragraph (e) of this section, all transactions otherwise prohibited by §§ 537.201 and 537.202 that are ordinarily incident to the movement of goods within Burma are authorized, provided the goods are not being sent to, from, or on behalf of a person whose property and interests in property are blocked pursuant to § 537.201(a).

(e) Paragraph (d) of this section does not authorize:

(1) The unblocking of any property or interests in property that were blocked pursuant to § 537.201(a).

(2) A U.S. financial institution to advise or confirm any financing by a person whose property and interests in property are blocked pursuant to § 537.201(a).

(f) For the purposes of this section, the term *non-financial services* means all services other than those listed in § 537.305.

Note to § 537.532: See § 537.529 for a general license authorizing the exportation or reexportation of financial services to Burma.

Dated: May 13, 2016.

John E. Smith,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2016–11677 Filed 5–17–16; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0406]

Drawbridge Operation Regulation; Lake Champlain, North Hero Island, VT

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the US2 Bridge across Lake Champlain (The Gut), mile 91.8, between North Hero and South Hero Island, Vermont. This deviation is necessary to allow the bridge owner to perform mechanical and electrical repairs at the bridge.

DATES: This deviation is effective without actual notice from May 18, 2016 to 8 a.m. on June 15, 2016. For the purposes of enforcement, actual notice will be used from 8 a.m. on May 15, 2016, until May 18, 2016.

ADDRESSES: The docket for this deviation, USCG–2016–0406, is available at *http://www.regulations.gov.* Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Jim Rousseau; Project Officer, First Coast Guard District, telephone (617) 223–8619, email *james.l.rousseau2@uscg.mil.*

SUPPLEMENTARY INFORMATION: The US2 Bridge across Lake Champlain, at North Hero Island, Vermont, has a vertical clearance in the closed position of 18 feet at mean high water. The existing bridge operating regulations are found at 33 CFR 117.993(b).

The subject waterway is typically transited by seasonal, recreational vessels of various sizes. Several marina facilities are in the area of the bridge with local vessels requesting bridge openings several times a week.

The bridge owner, Vermont Agency of Transportation, requested a temporary deviation from the normal operating schedule to facilitate mechanical and electrical repairs at the bridge. In response to the request, the Coast Guard's First District has approved a deviation from 8 a.m. on May 15, 2016 until 8 a.m. June 15, 2016.

During the time of this temporary deviation, the US2 Bridge shall open on signal on the hour, but it will not open on the half hour. Also during the time of this temporary deviation, the US2 Bridge will be open by use of an auxiliary drive system not designed for high-speed openings, which means the bridge will open more slowly than it does under normal operations.

Vessels that are able to pass under the bridge in the closed position may do so at anytime. The bridge will be able to open for emergencies, and there is an alternate route for vessels to pass to the north under the Alburg Passage US2 fixed bridge, which has a vertical clearance of 26 feet at mean high water.

The Coast Guard will inform the users of the waterways through our Local Notice and Broadcast to Mariners of the change in operating schedule for the bridge so that vessel operations can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: May 13, 2016,

C.J. Bisignano,

Supervisory Bridge Management Specialist, First Coast Guard District.

[FR Doc. 2016–11713 Filed 5–17–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0018, EPA–HQ–OPP–2015–0020; FRL–9945–76]

Quaternary Ammonium Compounds, Benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium Salts With Sepiolite; and Quaternary Ammonium Compounds, Benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium Salts With Saponite; Exemptions From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite (CAS Reg. No. 1574487–61–8) when used as an inert ingredient (suspending or structuring agent) in pesticide formulations applied to growing crops at a concentration not to exceed 2.0% by weight in the formulation, asbestos free and containing less than 1% crystalline silica. This regulation also establishes an exemption from the requirement of a tolerance for residues of quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite (CAS Reg. No. 1588523–05–0) when used as an inert ingredient (suspending or structuring agent) in pesticide formulations applied to growing crops at a concentration not to exceed 1.0% by weight in the formulation. Technology Sciences Group on behalf of BYK Additives Inc. submitted petitions to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite.

DATES: This regulation is effective May 18, 2016. Objections and requests for hearings must be received on or before July 18, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The dockets for these actions, identified by docket identification (ID) number EPA–HQ–OPP–2015–0018, EPA–HQ–OPP–2015–0020 are available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2015–0018 (CAS Reg. No. 1574487–61–8), EPA–HQ–OPP–2015–0020 (CAS Reg. No. 1588523–05–0) in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 18, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0018, EPA–HQ–OPP–2015–0020 by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of April 6, 2015 (80 FR 18327) (FRL–9924–00), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of pesticide petitions (PP IN–10780) and (PP IN–10781) by Technology Sciences Group on behalf of BYK Additives Inc., 1600 West Hill Street, Louisville, KY 40210. The petitions requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite (CAS Reg. No. 1574487–61–8) when used as an inert ingredient suspending or structuring agent in pesticide formulations applied to growing crops with a limitation of 2.0% in formulation, asbestos free and containing less than 1% crystalline silica; and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite (CAS Reg. No. 1588523–05–0) when used as an inert ingredient suspending or structuring agent in pesticide formulations applied to growing crops with a limitation of 1.0% in formulation.

That document referenced a summary of the petitions prepared by Technology Science Group, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notices of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite, and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Specific information on the studies received and the nature of the adverse effects caused by both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Based on data in structurally similar quaternary ammonium clay substances, quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite have low acute toxicity via the oral, dermal and inhalation routes in rats. The substances are expected to be a slight skin and eye irritant. A structurally similar quaternary ammonium clay substance did not cause skin sensitization in guinea pigs.

Multiple 28-day repeat-dose studies consistently showed high No Observed

Adverse Effect Levels (NOAELs), typically the highest dose tested, which was 1,000 milligrams/kilogram/day (mg/kg/day) in rats. There was an absence of test substance-related toxicologically significant effects at any of the doses administered, including for neurological and immunological endpoints. Similarly, there were no effects on reproductive or developmental endpoints and no evidence for genotoxicity in multiple *in vitro* and *in vivo* assays (OECD 471, 474 and 476 on multiple quaternary ammonium compounds).

Clays treated with quaternary ammonium compounds have low water solubility, a high hydrophobic partition coefficient and relatively high molecular weight. All three factors indicate likely limited absorption following ingestion, dermal exposure or inhalation. Based on similarities to other quaternary ammonium clays (high molecular weights, low water solubility, high hydrophobicity), both benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite would also be almost completely eliminated from the body shortly after oral dosing. Therefore, the biological availability is expected to be low.

B. Toxicological Points of Departure/Levels of Concern

1. The available toxicity studies indicate that both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite have very low overall toxicity. The NOAELs were >1,000 mg/kg/day (limit dose). Since signs of toxicity were not observed at the limit dose an endpoint of concern for risk assessment purposes were not identified. Therefore, since no endpoint of concern was identified for the acute and chronic dietary exposure assessment and short and intermediate dermal and inhalation exposure, quantitative risk assessments for both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite are not necessary.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite in food as follows:

Under this exemption from the requirement of a tolerance, residues of quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite may be found on foods from crops that were treated with pesticide formulations containing both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite. However, quantitative dietary exposure assessments were not conducted since endpoints for risk assessment were not identified.

2. *Dietary exposure from drinking water.* Since hazard endpoints of concern were not identified for the acute and chronic dietary assessments, quantitative dietary exposure risk assessments for drinking water were not conducted, although exposures may be expected from use on food crops.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). Both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite may be used in pesticide products and non-pesticide products that may be used around the home. Based on the discussion in Unit IV.B., quantitative residential exposure assessments for both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite was not conducted.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has not found either quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite or with saponite to share a common mechanism of toxicity with any other substances, and both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. Based on the lack of toxicity of ammonium acetate in the available studies and its chemical properties, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite when used as an inert ingredient (suspending or structuring agent) with a limitation of 2.0% in formulation, asbestos free and containing less than 1% crystalline silica and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite when used as an inert ingredient (suspending or structuring agent) with a limitation of 1.0% in formulation, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.920 for residues of both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite when used as an inert ingredient in pesticide formulations applied to growing crops with a limitation of 2.0% in formulation, asbestos free and containing less than 1% crystalline silica and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite when used as an inert ingredient (suspending or structuring agent) with a limitation of 1.0% in formulation, is safe under FFDCA section 408.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite are not expected to pose an acute risk.

2. *Chronic risk.* A chronic aggregate risk assessment takes into account subchronic and chronic exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a subchronic or chronic oral exposure were identified and no chronic dietary endpoints were selected. Therefore, quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl) dimethylammonium salts with sepiolite is not expected to pose a chronic risk.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no short-term adverse effect was identified, both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite were not expected to pose short-term risks.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite were not expected to pose intermediate-term risks.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit IV.A., EPA does not expect either quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite or with saponite to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to either quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite or with saponite residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Although EPA is establishing a limitation on the amount of quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite; and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite that may be used in pesticide formulations, an analytical enforcement methodology is not necessary for this exemption from the requirement of tolerance. The limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide for sale or distribution for use on growing crops with concentrations of quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite exceeding 2.0% by weight of the formulation, asbestos free and containing less than 1% crystalline silica; and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite exceeding 1.0% by weight of the formulation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite, and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite.

VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established under 40 CFR 180. 920 for quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite (CAS Reg. No. 1574487–61–8) when used as an inert ingredient (suspending or structuring agent) in pesticide formulations applied to growing crops with a limitation of 2.0% in formulation, asbestos free and containing less than 1% crystalline silica; and for quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite (CAS Reg. No. 1588523–05–0) when used as an inert ingredient (suspending or structuring agent) in pesticide formulations applied to growing crops with a limitation of 1.0% in formulation.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 10, 2016.

G. Jeffery Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.920, add alphabetically the inert ingredients "Quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite" and "Quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite" to the table to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* *
Quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite (CAS Reg. No. 1588523–05–0).	Not to exceed 1.0% by weight of pesticide formulation.	Suspending or structuring agent.
Quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite (CAS Reg. No. 1574487–61–8).	Not to exceed 2.0% by weight of pesticide formulation, asbestos free and containing less than 1% crystalline silica.	Suspending or structuring agent.
* * *	* *	* *

[FR Doc. 2016–11743 Filed 5–17–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

48 CFR Parts 1503 and 1552

[EPA–HQ–OARM–2015–0662; FRL 9943–61–OARM]

Environmental Protection Agency Acquisition Regulation; Improper Business Practices and Personal Conflicts of Interest, Solicitation Provisions and Contract Clauses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is issuing a final rule to make administrative changes to the Environmental Protection Agency Acquisition Regulation (EPAAR). EPA does not anticipate any adverse comments.

DATES: This rule is effective on July 18, 2016 without further action, unless EPA receives adverse comment by June 17, 2016. If EPA receives adverse comment, a timely withdrawal will be published in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OARM–2015–0662, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Julianne Odend'hal, Policy, Training, and Oversight Division, Acquisition Policy and Training Service Center (3802R), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 564–5218; email address: *odend'hal.julianne@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Why is EPA using a direct final rule?

EPA is publishing this rule without a prior proposed rule because EPA views this as a noncontroversial action and anticipates no adverse comment. EPAAR parts 1503 and 1552 are amended to conform to the format of the Federal Acquisition Regulation (FAR) and to correct, clarify and update information. If EPA receives adverse comment, a timely withdrawal will be published in the **Federal Register** informing the public that the rule will not take effect. Any parties interested in commenting must do so at this time.

II. Does this action apply to me?

The EPAAR applies to contractors who have a contract with the EPA.

III. What should I consider as I prepare my comments for EPA?

A. *Submitting CBI.* Do not submit this information to EPA through *http://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI, and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

B. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

IV. Background

EPAAR parts 1503 and 1552 are amended to conform to the format of the Federal Acquisition Regulation (FAR) and to correct, clarify and update information.

V. Final Rule

This direct final rule makes the following changes: (1) Updates the title and clarifies the information in section 1503.101–370 including correcting statute citations; (2) corrects section number "1503.104–5" to read "1503.104–4" and corrects the reference to "FAR 3.104–5" to read "FAR 3.104–4"; (3) removes section 1503.408, *Evaluation of the SF 119,* because the form no longer exists; (4) updates the subpart number and title of "1503.5" including "1503.500–70", "1503.500–71" and "1503.500–72" to read "1503.10 Contractor Code of Business Ethics and Conduct", "1503.1002 Policy", "1503.1003 Requirements", and "1503.1004 Contract clause" to conform to the FAR, updates the reference to "EPAAR 1503.500–71(b)" to read "EPAAR 1503.1003(b)"; (5) replaces the term "regular employee" with "employee" which is defined at 5 U.S.C. 2505, and replaces the term "special employee" with "special government employee" which is defined at 18 U.S.C. 202 in sections 1503.600–71, 1503.601, and 1552.203–70; and (6) updates the EPA OIG contact information in section 1552.203–71.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the PRA because it does not contain any information collection activities.

C. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. This action amends EPAAR parts 1503 and 1552 to conform to the format of the Federal Acquisition Regulation (FAR) and to correct, clarify and update information. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). Thus, Executive Order 13175 does not apply to this action. In the spirit of Executive Order 13175, and consistent with EPA policy to promote communication between EPA and Tribal governments, EPA specifically solicits additional comment on this proposed rule from Tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act of 1995

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, (February 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment.

K. Congressional Review

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules (1) rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding this action under section 801 because this is a rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties.

List of Subjects in 48 CFR Parts 1503 and 1552

Government procurement.

Dated: May 2, 2016.

John R. Bashista,

Director, Office of Acquisition Management.

For the reasons stated in the preamble, 48 CFR parts 1503 and 1552 are amended as set forth below:

■ 1. Revise part 1503 to read as follows:

PART 1503—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

Sec.
1503.000 Scope of part.

Subpart 1503.1 Safeguards

1503.101–370 Financial conflicts of interest and loss of impartiality.
1503.104–4 Disclosure, protection, and marking of contractor bid or proposal information and source selection information.

Subpart 1503.6 Contracts With Government Employees or Organizations Owned or Controlled by Them

1503.600–70 Scope of subpart.
1503.600–71 Definitions.
1503.601 Policy.
1503.602 Exceptions.
1503.670 Disclosure provision.

Subpart 1503.9 Whistleblower Protections for Contractor Employees

1503.905 Procedures for investigating complaints.

Subpart 1503.10 Contractor Code of Business Ethics and Conduct

1503.1002 Policy.
1503.1003 Requirements.
1503.1004 Contract clause.

Authority: 5 U.S.C. 301 and 41 U.S.C. 418b.

1503.000 Scope of part.

This part implements FAR part 3, cites EPA regulations on employee responsibilities and conduct, establishes responsibility for reporting violations and related actions, and provides for authorization of exceptions to policy.

Subpart 1503.1—Safeguards

1503.101–370 Financial conflicts of interest and loss of impartiality.

(a) Each EPA employee (including special government employees as defined by 18 U.S.C. 202 and 1503.600–71(b)) engaged in source evaluation and selection is required to abide by and be familiar with the conflict of interest statutes codified in Title 18 of the United States Code, as well as the Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR part 2635.

(b) Pursuant to the financial conflict of interest statute, 18 U.S.C. 208 and 5 CFR part 2635, subparts D and E, each employee must abide by ethics requirements regarding financial conflict of interest and impartiality in performing official duties. The employee shall inform his or her Deputy Ethics Official and the Source Selection Authority (SSA) in writing if his/her participation in the source evaluation and selection process may raise possible or apparent conflict of interest or impartiality concerns. The employee must cease work on the source evaluation and selection process until the appropriate ethics official makes a determination. Please note that only the Office of General Counsel can direct employees to divest of financial interests or to recommend any waivers of the financial conflict of interest standards.

1503.104–4 Disclosure, protection, and marking of contractor bid or proposal information and source selection information.

(a)(1) The Chief of the Contracting Office (CCO) is the designated official to make the decision whether support contractors are used in proposal evaluation (as authorized at FAR 15.305(c) and restricted at FAR 37.203(d)).

(2) The following written certification and agreement shall be obtained from non-Government evaluator prior to the release of any proposal to that evaluator:

"Certification on the Use and Disclosure of Proposals"

RFP #:
Offeror:

1. I hereby certify that to the best of my knowledge and belief, no conflict of interest exists that may diminish my capacity to perform an impartial, technically sound, objective review of this proposal(s) or otherwise result in a biased opinion or unfair competitive advantage.

2. I agree to use any proposal information only for evaluation purposes. I agree not to copy any information from the proposal(s), to use my best effort to safeguard such information physically, and not to disclose the contents of nor release any information relating to the proposal(s) to anyone outside of the evaluation team assembled for this acquisition or individuals designated by the Contracting Officer.

3. I agree to return to the Government all copies of proposals, as well as any abstracts, upon completion of the evaluation.

Name and Organization:

Date of Execution:

(End of certificate)

(b) Information contained in proposals will be protected and disclosed to the extent permitted by law, and in accordance with FAR 3.104–4, 15.207, and Agency procedures at 40 CFR part 2.

Subpart 1503.6—Contracts With Government Employees or Organizations Owned or Controlled by Them

1503.600–70 Scope of subpart.

This subpart implements and supplements FAR subpart 3.6 and sets forth EPA policy and procedures for identifying and dealing with conflicts of interest and improper influence or favoritism in connection with contracts involving current or former EPA employees. This subpart does not apply to agreements with other departments or agencies of the Federal Government, nor to contracts awarded to State or local units of Government.

1503.600–71 Definitions.

(a) *Employee* means an EPA officer and an individual who is appointed in the civil service and engaged in the performance of a Federal function under authority of law or an Executive act. See 5 U.S.C. 2105.

(b) *Special government employee* means an officer or employee of EPA who is retained, designated, appointed or employed to perform, with or without compensation, for not to exceed 130 days during any period of 365 consecutive days, temporary duties either on a full-time or intermittent basis. See 18 U.S.C. 202.

1503.601 Policy.

(a) No contract may be awarded without competition to a former employee or special government employee (or to a business concern or other organization owned or substantially owned or controlled by a former employee) whose employment terminated within 365 calendar days before submission of a proposal to EPA.

(b) No contract shall be awarded without competition to a firm which employs, or proposes to employ, a current employee or special government employee, or a former EPA employee or special government employee, whose employment terminated within 365 calendar days before submission of a proposal to EPA, if either of the following conditions exists:

(1) The current or former EPA employee or special government employee is or was involved in development or negotiating the proposal for the prospective contractor; or

(2) The current or former EPA employee or special government employee will be involved directly or indirectly in the management, administration, or performance of the contract.

1503.602 Exceptions.

The Assistant Administrator for the Office of Administration and Resources Management may authorize an exception, in writing, to the policy in FAR 3.601 and 1503.601 for the reasons stated in FAR 3.602, if the exception would not involve a violation of 18 U.S.C. 203, 18 U.S.C. 205, 18 U.S.C. 207, 18 U.S.C. 208, the Standards of Ethical Conduct for Employees of the Executive Branch at 5 CFR part 2635, or the EPA supplemental regulations at 5 CFR part 6401. The Assistant Administrator shall consult with the Designated Agency Ethics Official before authorizing any exceptions.

1503.670 Disclosure provision.

The Contracting Officer shall insert the provision at 1552.203–70, *Current/Former Agency Employee Involvement Certification,* in all solicitations for sole-source acquisitions.

Subpart 1503.9—Whistleblower Protections for Contractor Employees

1503.905 Procedures for investigating complaints.

The Assistant Administrator for the Office of Administration and Resources Management is designated as the recipient of the written report of findings by the Inspector General. The Assistant Administrator shall ensure that the report of findings is disseminated in accordance with FAR 3.905(c).

Subpart 1503.10—Contractor Code of Business Ethics and Conduct

1503.1002 Policy.

Government contractors must conduct themselves with the highest degree of integrity and honesty. Contractors should have standards of conduct and internal control systems that:

(a) Are suitable to the size of the company and the extent of their involvement in Government contracting;

(b) Promote such standards;

(c) Facilitate timely discovery and disclosure of improper conduct in connection with Government contracts; and

(d) Ensure corrective measures are promptly instituted and carried out.

1503.1003 Requirements.

(a) A contractor's system of management controls should provide for:

(1) A written code of business ethics and conduct and an ethics training program for all employees;

(2) Periodic reviews of company business practices, procedures, policies and internal controls for compliance with standards of conduct and the special requirements of Government contracting;

(3) A mechanism, such as a hotline, by which employees may report suspected instances of improper conduct, and instructions that encourage employees to make such reports;

(4) Internal and/or external audits, as appropriate;

(5) Disciplinary action for improper conduct;

(6) Timely reporting to appropriate Government officials of any suspected or possible violation of law in connection with Government contracts or any other irregularities in connection with such contracts; and

(7) Full cooperation with any Government agencies responsible for either investigation or corrective actions.

(b) Contractors who are awarded an EPA contract of $1 million or more must display EPA Office of Inspector General Hotline Posters unless the contractor has established an internal reporting mechanism and program as described in paragraph (a) of this section.

1503.1004 Contract clause.

As required by EPAAR 1503.1003(b), the contracting officer shall insert the clause at 1552.203–71, *Display of EPA Office of Inspector General Hotline Poster,* in all contracts valued at $1,000,000 or more, including all contract options.

PART 1552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 2. The authority citation for part 1552 is revised to read as follows:

Authority: 5 U.S.C. 301 and 41 U.S.C. 418b.

■ 3. Revise section 1552.203–70 to read as follows:

1552.203–70 Current/former agency employee involvement certification.

As prescribed in 1503.670, insert the following provision in all EPA solicitations for sole-source acquisitions.

Current/Former Agency Employee Involvement Certification Jul 2016

The offeror (quoter) hereby certifies that:

(a) He/She is [] is not [] a former employee or special government employee whose EPA employment terminated within one year prior to submission of this offer (quote).

(b) He/She does [] does not [] employ or propose to employ a current/former employee or special government employee whose EPA employment terminated within one year prior to submission of this offer (quote) and who has been or will be involved, directly or indirectly, in developing or negotiating this offer (quote) for the offeror (quoter), or in the management, administration or performance of any contract resulting from this offer (quote).

(c) He/She does [] does not [] employ or propose to employ as a consultant or subcontractor under any contract resulting from this offer (quote) a current/former employee or special government employee whose EPA employment terminated within one year prior to submission of this offer (quote).

(d) A former employee or special government employee whose EPA employment terminated within one year prior to submission of this offer (quote) or such former employee's spouse or minor child does [] does not [] own or substantially own or control the offeror's (quoter's) firm.

(e) See EPAAR part 1503.600–71 for definitions of the terms "employee" and "special government employee."

(End of provision)

■ 4. Revise section 1552.203–71 to read as follows:

1552.203–71 Display of EPA Office of Inspector General Hotline poster.

As prescribed in 1503.1004, insert the following clause in all contracts valued at $1,000,000 or more including all contract options.

Display of EPA Office of Inspector General Hotline Poster Jul 2016

(a) For EPA contracts valued at $1,000,000 or more including all contract options, the contractor shall prominently display EPA Office of Inspector General Hotline posters in contractor facilities where the work is performed under the contract.

(b) Office of Inspector General hotline posters may be obtained from the EPA Office of Inspector General, ATTN: OIG Hotline (2443), 1200 Pennsylvania Avenue NW., Washington, DC 20460, or by accessing the OIG Web site at: *http://www.epa.gov/oig/hotline.html.*

(c) The Contractor need not comply with paragraph (a) of this clause if it has established a mechanism, such as a hotline, by which employees may report suspected instances of improper conduct, and has provided instructions that encourage employees to make such reports.

(End of clause)

[FR Doc. 2016–11509 Filed 5–17–16; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 81, No. 96
Wednesday, May 18, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 5, 92, 93, 570, 574, 578, 880, 881, 883, 884, 886, 891, 905, 983

[Docket No. FR 5890–P–01]

RIN 2501–AD75

Narrowing the Digital Divide Through Installation of Broadband Infrastructure in HUD-Funded New Construction and Substantial Rehabilitation of Multifamily Rental Housing

AGENCY: Office of the Secretary, HUD.

ACTION: Proposed rule.

SUMMARY: Through this proposed rule, HUD continues its efforts to narrow the digital divide in low-income communities served by HUD by providing, where feasible and with HUD funding, broadband infrastructure to communities in need of such infrastructure. Broadband is the common term used to refer to a very fast connection to the Internet. Such connection is also referred to as high-speed broadband, broadband Internet, or high-speed Internet. In this proposed rule, HUD proposes to require installation of broadband infrastructure at the time of new construction or substantial rehabilitation of multifamily rental housing that is funded or supported by HUD. Installation of broadband infrastructure at the time of new construction or substantial rehabilitation is generally easier and less costly than when such installation is undertaken as a stand-alone effort. The proposed rule, however, recognizes that installation of broadband infrastructure may not be feasible for all new construction or substantial rehabilitation, and, therefore, the proposed rule allows limited exceptions to the installation requirements. Installing unit-based broadband infrastructure in multifamily rental housing that is newly constructed or substantially rehabilitated with or supported by HUD funding will provide a platform for individuals and families residing in such housing to participate in the digital economy, and increase their access to economic opportunities.

DATES: *Comment due date:* July 18, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule. All communications must refer to the above docket number and title. To receive consideration as public comments, comments must be submitted through one of the two methods specified below.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make comments immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

No Facsimiled Comments. Facsimiled (faxed) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number). Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For Community Planning and Development programs, Marion McFadden, Office of Community Planning and Development, Room 7204, telephone, 202–708–2111 (this is not a toll-free number). For Office of Multifamily Housing programs, Katie Buckner, Office of Housing, Room 6222, telephone 202–402–7140 (this is not a toll-free number). For Office of Public and Indian Housing programs, Dominique Blom, Office of Public and Indian Housing, Room 4130, telephone 202–402–4181 (this is not a toll-free number). The address for all individuals is Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410–0500. Persons with hearing or speech impairments may access these numbers through TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of This Proposed Rule

The purpose of this proposed rule is to require installation of broadband infrastructure at the time of new construction or substantial rehabilitation of multifamily rental housing that is funded or supported by HUD.[1] This rulemaking does not require a HUD-funded grantee to undertake new construction or substantial rehabilitation, but when a grantee does choose to pursue such activity for multifamily rental housing with HUD funding, this proposed rule would require installation of broadband infrastructure. While the proposed rule only requires affected grantees to install one form of broadband infrastructure, HUD suggests that grantees consider whether installing more than one form of broadband infrastructure would be beneficial to encourage competition among service providers on quality and price. Installing unit-based broadband infrastructure in multifamily rental housing that is newly constructed and substantially rehabilitated with or supported by HUD funding will provide a platform for individuals and families residing in such housing to participate in the digital economy, and increase their access to economic opportunities.

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[1] This proposed rule applies to all projects with project-based Section 8 housing assistance payment (HAP) contracts (other than Mod Rehab or Mod Rehab Single Room Occupancy (SRO) projects), regardless of whether the properties receive specific funding to pay directly for substantial rehabilitation or new construction, as defined in this proposed rule.

B. Summary of Major Provisions of This Proposed Rule

This proposed rule would require installation of broadband infrastructure at the time of new construction or substantial rehabilitation of multifamily rental units funded by the following programs:

1. Choice Neighborhoods Implementation Grant program;
2. Community Development Block Grant (CDBG) program, including the CDBG Disaster Recovery program;
3. Continuum of Care program;
4. HOME Investment Partnerships program;
5. Housing Opportunities for Persons With AIDS program;
6. Housing Trust Fund program;
7. Project-Based Voucher program;
8. Public Housing Capital Fund program;
9. Section 8 project-based housing assistance payments programs, including, but not limited to, the Section 8 New Construction, Substantial Rehabilitation, Loan Management Set-Aside, and Property Disposition programs; and
10. Supportive Housing for the Elderly and Persons with Disabilities program.

The requirements of the proposed rule would not apply to multifamily rental housing that only has a mortgage insured by HUD's Federal Housing Administration or with a loan guaranteed under a HUD loan guarantee program.

HUD is proposing to define broadband infrastructure as cables, fiber optics, wiring, or other permanent infrastructure, including wireless infrastructure, as long as the installation results in broadband infrastructure in each dwelling unit meeting the definition created by the Federal Communications Commission (FCC), which currently is 25 Megabits per second (Mbps) download, 3 Mbps upload. In addition, HUD is proposing that, for programs that do not already have a definition of substantial rehabilitation, substantial rehabilitation be defined as work on the electrical system that is equal to or greater than 75 percent of the cost of replacing the entire electrical system, or when the cost of the rehabilitation is equal to or greater than 75 percent of the total estimated cost of replacing the multifamily rental housing after the rehabilitation is complete.

C. Costs and Benefits of This Proposed Rule

The costs and benefits of this proposed rule are difficult to quantify, but they can be described qualitatively. This proposed rule only requires that the broadband infrastructure provided is to receive high-speed Internet that is "accessible" in each unit; it does not require those recipients of funding undertaking new construction or substantial rehabilitation to provide a regular subscription to broadband service (even at a cost) to current or future residents. Furthermore, the definition of broadband infrastructure in the proposed rule is broad enough to include coaxial cable television (TV) wiring that supports cable modem access or even permanent infrastructure that would provide broadband speeds to dwelling units wirelessly. The rulemaking also provides for exceptions to the installation requirements for where the installation is too costly to provide due to location or building characteristics.

A recent survey by the National Association of Homebuilders found that just 4 percent of the surveyed multifamily housing developers never installed landline wires and jacks in multifamily units completed in the past 12 months.[2] In recent years, HUD's competitive grants for new construction under the Choice Neighborhoods program have sought the provision of broadband access. Therefore, this rulemaking simply proposes to codify what is considered common practice in the private market today when new construction or substantial rehabilitation is undertaken.

Given the wide range of technologies that may be employed to meet the requirements of this proposed rule, it is not possible to specify the cost of the technology and how much additional burden this may be for owners or developers building or providing substantial rehabilitation to HUD-assisted rental housing. If the broadband infrastructure is wiring connected to proximate telephone or cable company networks, the cost is not expected to be significant, as all electrical work in a multifamily project is estimated to be only about 10 percent of the construction cost;[3] running an additional cable through existing electrical conduits would be a minimal incremental cost. If the broadband infrastructure is wireless, the cost will be for the equipment, which varies greatly by the design and size of the project, as does the cost per unit. Given that the costs of installation of broadband infrastructure are only a portion of the 10 percent of construction costs, the requirement proposed by this rulemaking is not expected to measurably reduce the size of the housing or the number of units to be constructed. At most, installation of broadband infrastructure may reduce the provision of other amenities or nonessential finishes, but HUD considers even these reductions. Additionally, the proposed rule only applies to new construction or substantial rehabilitation that is supported with HUD-provided resources.

Materials on the benefits of narrowing the digital divide are voluminous. Having broadband Internet in the home increases household income[4] and yields higher education achievement for students.[5] On July 2015, the Council of Economic Advisers issued the report "Mapping the Digital Divide," which examines progress in the United States in narrowing the digital divide and the work that still needs to be done, especially in the Nation's poorest neighborhoods and most rural communities.[6] However, this proposed rule's limited scope in only requiring the installation of infrastructure instead of providing Internet access also limits the benefits of the proposed rule. The benefit of the proposed rule is that where broadband Internet service can be made available, the tenant, residing in housing with broadband infrastructure, will be assured of the ability to access broadband Internet service, whether they choose and are able to afford Internet service or not. This puts broadband Internet service within reach, especially where other charitable and public social programs, including HUD's ConnectHome program, provide free or reduced-cost service.

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[2] NAHB, Multifamily Market Survey 3rd Quarter 2015. November 2015. There were 90 responses, and of the responses, 18 percent indicated it was Not Applicable, presumably because they had not completed any projects in the past 12 months. The survey covers all multifamily construction including lower quality Class B and Class C. It does not provide details on the developers or projects that did not install landlines.

[3] *2015 National Building Cost Manual.* Ed. Ben Moselle. Carlsbad, CA: Craftsman Book Company. *https://www.craftsman-book.com/media/static/previews/2015_NBC_book_preview.pdf,* pg. 19.

[4] Ericsson, Arthur D. Little, and Chalmers University of Technology. Socioeconomic Effects of Broadband Speed. September 2013. *http://www.ericsson.com/res/thecompany/docs/corporate-responsibility/2013/ericsson-broadband-final-071013.pdf.*

[5] Davidson, Charles M. and Michael J. Santorelli. "The Impact of Broadband on Education." December 2010. *https://www.uschamber.com/sites/default/files/legacy/about/US_Chamber_Paper_on_Broadband_and_Education.pdf,* pg. 24.

[6] See Council of Economic Advisers. "Mapping the Digital Divide." *Issue Brief.* July 2015. *https://www.whitehouse.gov/sites/default/files/wh_digital_divide_issue_brief.pdf.*

II. Background

On March 23, 2015, President Obama issued a Presidential memorandum on "Expanding Broadband Deployment and Adoption by Addressing Regulatory Barriers and Encouraging Investment and Training." [7] In this memorandum, the President noted that access to high-speed broadband is no longer a luxury, but it is a necessity for American families, businesses, and consumers. The President further noted that the Federal Government has an important role to play in developing coordinated policies to promote broadband deployment and adoption, including promoting best practices, breaking down regulatory barriers, and encouraging further investment.

On July 15, 2015, HUD launched its Digital Opportunity Demonstration, known as "ConnectHome," in which HUD provided a platform for collaboration among local governments, public housing agencies, Internet service providers, philanthropic foundations, nonprofit organizations, and other relevant stakeholders to work together to produce local solutions for narrowing the digital divide in communities across the nation served by HUD. The demonstration, or pilot, commenced with the participation of 28 communities.[8] Through contributions made by the Internet service providers and other organizations participating in the pilot, residents living in public and HUD-assisted housing in these 28 communities will receive discounted broadband service, technical assistance, literacy training, and electronic devices that provide for accessing high-speed Internet.

The importance of all Americans having access to the Internet cannot be overstated. As HUD stated in its announcement of the Digital Opportunity Demonstration, published in the **Federal Register** on April 3, 2015, at 80 FR 18248, knowledge is a pillar to achieving the American Dream—a catalyst for upward mobility as well as an investment that ensures each generation has opportunities to succeed. Many low-income Americans do not have broadband Internet at home, contributing to the estimated 66 million Americans who lack basic digital literacy skills.[9] Without broadband adoption and the skills to use Internet technology at home, children and adults can miss out on the high-value educational, economic, and social impact that high-speed Internet provides. It is for these reasons that HUD is exploring ways, beyond ConnectHome, to narrow the digital divide for the low-income individuals and families served by HUD multifamily rental housing programs. This proposed rule presents one such additional effort.

III. This Proposed Rule

A. Multifamily Rental Housing Covered by This Proposed Rule

This proposed rule would apply to new construction and substantial rehabilitation of multifamily rental housing in the HUD programs that authorize and fund such activities. These programs are listed in Section II.B of this preamble. The proposed rule would not apply to multifamily rental housing with a mortgage insured by HUD's Federal Housing Administration (FHA) or with a loan guaranteed under a HUD loan guarantee program.[10] Further, this proposed rule would not apply to new construction or substantial rehabilitation of single-family or single-unit housing.

HUD proposes to require installation of broadband infrastructure in individual housing units at the time of new construction or substantial rehabilitation of multifamily rental housing, because while such installation is not without cost, the cost can be reduced by providing the installation at the time when housing is first being built or substantially rehabilitated.

B. HUD Programs Covered by This Proposed Rule

As provided in section I.B. of this preamble, this proposed rule would apply to multifamily rental housing that is to be newly constructed or substantially rehabilitated with funds under the following HUD programs, as implemented through the regulations or under authorities cited below:

1. Choice Neighborhoods Implementation Grant program, for which the requirements are found in HUD notices of funding availability (NOFAs);
2. Community Development Block Grant (CDBG) program, for which the regulations are found in 24 CFR part 570;
3. Continuum of Care (CoC) program, for which the regulations are found in 24 CFR part 578;
4. HOME Investment Partnerships (HOME) program, for which the regulations are found in 24 CFR part 92;
5. Housing Opportunities for Persons With AIDS (HOPWA) program, for which the regulations are found in 24 CFR part 574;
6. Housing Trust Fund (HTF) program, for which the regulations are found in 24 CFR part 93;
7. Project-Based Voucher program, for which the regulations are found in 24 CFR part 983;
8. Public Housing Capital Fund program, for which the regulations are found in 24 CFR part 905;
9. Section 8 project-based housing assistance payments programs, including, but not limited to, the Section 8 New Construction, Substantial Rehabilitation, Loan Management Set-Aside, and Property Disposition programs; and
10. Supportive Housing for the Elderly and Persons with Disabilities program, for which the regulations are found in 24 CFR part 891.

One of HUD's major new construction and substantial rehabilitation programs, the Choice Neighborhoods program, already requires broadband infrastructure in new construction units and permits the use of Choice Neighborhood funds for broadband infrastructure in substantially rehabilitated units. In addition, Choice Neighborhood grantees may use up to 15 percent of their grants for Critical Community Improvements, of which neighborhood broadband programs are considered an eligible expense. The Choice Neighborhoods program supports locally driven strategies to address struggling neighborhoods with distressed public or HUD-assisted housing through a comprehensive approach to neighborhood transformation. The program is designed to catalyze critical improvements in neighborhood assets, including vacant property, housing, services, and schools. One of the three core goals of the Choice Neighborhoods program is to replace distressed public and assisted housing with high-quality, mixed-income housing.[11] The Choice Neighborhoods program is implemented through annual NOFAs. HUD's Fiscal Year (FY) 2014 Choice Neighborhoods NOFA requires housing to be built with broadband Internet infrastructure.[12]

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[7] See Barack Obama. "Presidential Memorandum—Expanding Broadband Deployment and Adoption by Addressing Regulatory Barriers and Encouraging Investment and Training." March 23, 2015. *https://www.whitehouse.gov/the-press-office/2015/03/23/presidential-memorandum-expanding-broadband-deployment-and-adoption-addr.*

[8] See Connect Home. "About the Pilot." *http://connecthome.hud.gov/pilot.*

[9] See Connect Minnesota. "Digital Literacy: A Critical Skill for all Minnesotans." July 2013. *http://www.connectednation.org/sites/default/files/mn_digital_literacy_final.pdf.*

[10] See the Section 108 Loan Guarantee program, for which the regulations are found in 24 CFR part 570, subpart M; the Loan Guarantee program for Indian Housing, for which the regulations are found in 24 CFR part 1005; the Section 184 Loan Guarantees for Native Hawaiian Housing, for which the regulations are found in 24 CFR part 1007; and the Title VI Loan Guarantee Program, for which the regulations are found in 24 CFR part 1000, subpart E.

C. When Installation of Broadband Infrastructure May Be Infeasible

As noted in the Summary, HUD recognizes that installation of broadband infrastructure will not be feasible for every new construction or substantial rehabilitation of multifamily rental housing proposed to be covered by this proposed rule. For example, HUD recognizes that constructing or undertaking substantial rehabilitation of multifamily rental housing in certain areas may make installation of broadband infrastructure infeasible. As the Rural Utilities Service of the U.S. Department of Agriculture (USDA) stated in a final rule entitled "Economic Benefits of Broadband Deployment in Rural Areas," published on February 6, 2013,[13] bringing broadband services to rural areas presents challenges because rural systems must contend with lower household density than urban systems. Similarly, the particular type or structure of covered multifamily rental housing to be substantially rehabilitated may also make the installation of broadband infrastructure infeasible. The proposed rule therefore offers exceptions to broadband installation requirements when a funding recipient determines that installing broadband infrastructure is not feasible. Recipients and owners will be responsible for maintaining documentation that justifies the recipient's determination of infeasibility. HUD will consider providing additional guidance on this issue when the final rule becomes effective.

D. Rule Terminology

Broadband

As noted in the Summary, "broadband" is the common term used to refer to a very fast connection to the Internet. Such connection is also referred to as high-speed broadband or high-speed Internet. HUD recognizes that broadband is defined by several agencies as Internet access of at least a certain speed.[14] HUD is proposing to require that, where feasible, infrastructure be installed to provide every housing unit covered by this proposed rule with the ability to access the Internet that meets the definition adopted by the FCC—currently 25 Mbps download, 3 Mbps upload— regardless of whether any Internet service provider offers such access in a given location. This will provide the capacity for future broadband adoption without having to undertake additional renovation work. If the FCC modifies its definitions in the future, HUD's requirements for any new construction or substantial rehabilitation undertaken after the definition change will also change.

Broadband Infrastructure

The broadband infrastructure that needs to be installed to provide families in covered multifamily rental housing with broadband access will vary according to the housing being constructed or rehabilitated and the plans of the entity doing such construction or rehabilitation. Therefore, HUD proposes a flexible definition, allowing entities undertaking new construction or substantial rehabilitation to install the broadband infrastructure that is most feasible given the specifics of the construction or substantial rehabilitation to be undertaken. HUD proposes to require installation of cables, fiber optics, wiring, or other infrastructure, as long as the installation results in broadband accessibility in each dwelling unit. HUD proposes only to require the installation of broadband infrastructure on the property, not to require that grantees be responsible for ensuring an external connection between the property and an Internet service provider (ISP).

Substantial Rehabilitation

While some of the HUD programs listed in Section II.B of this preamble define what is meant by "substantial rehabilitation," the majority of the covered programs do not define this term. Therefore, for the sole purpose of determining when substantial rehabilitation of covered multifamily rental housing would trigger installation of broadband infrastructure and, except in the HOPWA program, where substantial rehabilitation is already defined, HUD proposes to define "substantial rehabilitation" to mean:

(1) Significant work on the electrical system of the multifamily rental housing. "Significant work" is defined as work that is equal to or greater than 75 percent of the cost of replacing the entire electrical system. In the case of multifamily rental housing with multiple buildings with more than 4 units, "entire system" refers to the electrical system of the building(s) undergoing rehabilitation; or

(2) Rehabilitation of the multifamily rental housing in which the estimated cost of the rehabilitation is equal to or greater than 75 percent of the total estimated cost of replacing the multifamily rental housing after the rehabilitation is complete. In the case of multifamily rental housing with multiple buildings with more than 4 units, the replacement cost used in this determination would be the replacement cost of the building(s) undergoing rehabilitation.

E. Compliance Timeline

HUD intends for this proposed rule to apply to projects that have not yet established their budgets and had funding approved, in order to give recipients and owners adequate time to factor the installation of broadband infrastructure into their new construction or substantial rehabilitation plans.

F. Rule's Objective

With this proposed rule, HUD seeks to take another important step toward narrowing the digital divide by providing residents in covered multifamily rental housing that is to be newly constructed or substantially rehabilitated with infrastructure that supports access to broadband Internet service, thereby increasing access to educational and economic opportunities for these residents.

IV. Specific Questions for Comments

While HUD welcomes comments on all aspects of this proposed rule, HUD is seeking specific comment on the following questions:

1. In light of the policy objectives discussed in the preamble, should this proposed rule be applied to other HUD programs, particularly additional multifamily housing programs (such as Rental Supplement (RS), Rental Assistance Payment (RAP), Moderate Rehabilitation Programs (Mod Rehab), etc.) or programs addressing single-family housing? Should any programs covered by this proposed rule be removed?

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[11] United States Department of Housing and Urban Development. "Choice Neighborhoods." *http://portal.hud.gov/hudportal/HUD?src=/program_offices/public_indian_housing/programs/ph/cn.*

[12] See United States Department of Housing and Urban Development. "Choice Neighborhoods Planning Grants Notice of Funding Availability." June 4, 2014. *http://portal.hud.gov/hudportal/documents/huddoc?id=13CNP-FR5800N13.pdf.*

[13] *http://www.gpo.gov/fdsys/pkg/FR-2013-02-06/pdf/2013-02390.pdf.*

[14] For example, see the U.S. Department of Agriculture definition at 7 CFR 1738.2 (requiring download speeds of at least 4 Mbps, or the Federal Communications Commission's definition in its 2015 Broadband Progress Report at *https://apps.fcc.gov/edocs_public/attachmatch/FCC-15-10A1.pdf* (defining broadband as having download speeds of at least 25 Mbps).

2. Given that the definition of the term "substantial rehabilitation" will determine which projects (other than new construction) are affected by this rulemaking, should the definition be changed in any way?

3. How much does it cost to add the installation of broadband infrastructure to a pre-planned new construction or rehabilitation project? Are HUD's estimates for the labor and materials costs for installing broadband infrastructure accurate? What data can the public share with HUD about the most cost-effective way for broadband infrastructure to be installed during a new construction or rehabilitation project?

4. The proposed rule provides exceptions to the requirements if compliance would be infeasible due to cost, location, or structural concerns. Are these exceptions too broad or too narrow? What is the best way for grantees to demonstrate to HUD that installation of broadband infrastructure is infeasible, and what would appropriate sanctions be if grantees do not comply even if it was feasible? Do any grantees have experience with a project in which installing broadband infrastructure was physically or economically infeasible, and under what circumstances was it infeasible?

5. When evaluating whether the rehabilitation being done meets the threshold in the definition of substantial rehabilitation, should HUD use the pre-rehabilitation estimates for the project alone, or should HUD include increases in rehabilitation costs that arise in the process of rehabilitation?

V. Findings and Certifications

Regulatory Review—Executive Orders 12866 and 13563

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory Review) directs executive agencies to analyze regulations that are "outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. This proposed rule was determined to be a "significant regulatory action" as defined in section 3(f) of the Executive order (although not an economically significant regulatory action, as provided under section 3(f)(1) of the Executive order).

As discussed, this proposed rule furthers HUD's efforts to narrow the digital divide in low-income communities served by HUD. Specifically, HUD proposes to require installation of broadband infrastructure at the time of new construction or substantial rehabilitation of multifamily rental housing that is funded by HUD. As noted in the Executive Summary, the costs and benefits of this proposed rule are difficult to quantify, but they can be described qualitatively.

A. Benefits

The evidence demonstrating the benefits of narrowing the digital divide is well documented. In just one example, a study conducted by a former Chair of the President's Council of Economic Advisers used data on the amount of time Internet users spend online to estimate that Internet access produces thousands of dollars of consumer surplus per user each year.[15] As noted above, however, the benefits of Internet technology have not been evenly distributed and research shows that there remain substantial disparities in both Internet use and the quality of access. This digital deficit is generally concentrated among older, less educated, and less affluent populations.[16]

HUD recognizes that the proposed rule's limited scope in only requiring the installation of infrastructure, instead of providing Internet access, also limits the benefits of the proposed rule. Specifically, the benefit of the proposed rule is that where broadband Internet can be made available at a limited price, the tenant, residing in housing with broadband infrastructure, will be assured of the ability to access broadband Internet service, whether they choose and are able to afford Internet service or not. This proposed rule, therefore, would put broadband Internet service within reach where other charitable and public social programs, including HUD's ConnectHome program, provide free or reduced cost service.

B. Costs

It is not possible to specify the exact costs that recipients and owners may incur as a result of the proposed rule, given the variety of available technologies that may be used to satisfy the new broadband requirements. However, available data indicates that any costs associated with this proposed rule will be minimal.

As is displayed on table I, broadband Internet access can be provided using two general technologies: Wired and wireless, each with several specific technologies. Broadband can be delivered over wired lines using very-high-bit-rate digital subscriber lines (VDSL), cable lines, power lines (BPL), or fiber optic platforms. Using wireless technologies, broadband can be provided using satellite, fixed wireless, mobile wireless, and Wi-Fi platforms.

TABLE I—TYPES OF BROADBAND TECHNOLOGIES

Platform	Connection type	Access requirement	
		Part of infrastructure	Not part of infrastructure
Wired			
Digital Subscriber Line (VDSL)	Copper wire	Yes	Router & Modem.
Cable Modem	Copper wire	Yes	Router & Modem.
Fiber	Fiber Optic wire	Yes	Router & Modem.
Broadband over Power Lines (BPL)	Copper wire	Yes	Router & Modem.
Wireless			
Satellite	Over the Air—satellite	None	Router & Modem.

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[15] Council of Economic Advisers July 2015 report, *supra*, citing Austan Goolsbee and Peter J. Klenow, *Valuing Consumer Products by the Time Spent Using Them: An Application to the Internet* National Bureau of Economic Research Working Paper No. 11995 (February 2006) available online at: *http://www.nber.org/papers/w11995.*

[16] Ibid.

TABLE I—TYPES OF BROADBAND TECHNOLOGIES—Continued

Platform	Connection type	Access requirement	
		Part of infrastructure	Not part of infrastructure
Fixed Wireless	Over the Air—Longer Range Directional Equipment.	None	Router & Modem.
Mobile Wireless	Over the Air—Cellular	None	Router & Modem.
Wireless Fidelity (WiFi)	Over the Air—Short-Range Wireless Technology.	None	Router & Modem.

Whereas wired lines technologies may require some sort of physical infrastructure consisting of internal wiring within the dwelling unit, wireless technologies do not require any additional physical infrastructure within the building. With wireless technology, the signal travels through the air to the customer, who uses a connection technology, such as a modem, to access the services. For wireless technologies, the infrastructure cost to the property boundary (connection to the service provider) is nil ($0). However, the availability of wireless broadband service is limited and evolving, so HUD expects many builders will opt to install wired broadband infrastructure.

Building costs of installing wired infrastructure are limited to in-dwelling wiring, as this is all that is required by the proposed rule. Within the unit or the building, the electrical work consists of running cable (meeting the requirements of category (Cat) 5e or Cat 6 wire), installing jacks and plates, and minor construction work (such as drilling and patching walls). Fiber optic cables are rarely run in the dwelling unit but are installed by the service provider outside the unit; the non-fiber optic wiring then makes broadband accessible within the unit. Depending on the market, some of the cost is also born by the service provider.

The average per-unit cost for wiring for broadband Internet is approximately $200[17] (see table II). These costs are simply estimates of one method of complying with the requirements of the proposed rule. Labor costs will also vary based on the region and whether the installation is being done as part of substantial rehabilitation or new construction. At most, installation of broadband infrastructure may reduce the provision of other amenities or nonessential finishes, but even these reductions are considered unlikely.

TABLE II—SAMPLE COST TO INSTALL ELECTRICAL WIRING (1 WIRING)

Item	Quantity	Low	High
Electrical Wiring Labor (Hours) Labor estimate to install electrical wiring, route, secure, and connect new NMB–B wiring run for single receptacle, up to a 40' run. Includes planning, equipment, and material acquisition, area preparation and protection, setup and cleanup.	2.1 hours	$160.07	$205.10
Electrical Wiring Materials and Supplies Cost of related materials and supplies typically required to install electrical wiring including connectors, fittings, and mounting hardware.	1 Wiring (unit)	20.00	25.00
Total Costs (1 Wiring)		180.07	230.10

HUD also notes that the proposed rule is drafted so as to minimize the costs of the new installation requirements. For example, the proposed rule does not mandate any rehabilitation or construction, and the decision to undertake such activities appropriately remains with recipients and owners. Rather, the scope of the proposed regulatory changes is limited to requiring the installation of broadband infrastructure if the recipient or owner elects to undertake new construction or substantial rehabilitation. The proposed rule minimizes the economic impacts on recipients and owners by recognizing that the installation of broadband infrastructure is generally less burdensome and costly at the time of new construction or substantial rehabilitation than when such installation is undertaken as a stand-alone effort.

Moreover, this proposed rule only requires the installation of broadband infrastructure that is "accessible" in each unit. The proposed rule does not require recipients or owners to provide a regular subscription to broadband Internet service (even at a cost) to residents. Also minimizing the economic costs of the proposed regulatory changes is the fact that the proposed definition of broadband infrastructure is broad enough to include cable television, fiber optic cabling, and wireless infrastructure providing appropriate broadband connectivity to the individual units. As discussed above in this Executive Summary, multifamily HUD or standard- market new construction typically provides telephone landline and cable TV connectivity. Further, HUD's competitive grants for new construction under the Choice Neighborhoods program have, in recent years, sought the provision of broadband.

A review of HUD internal databases, summarized on table III, shows that in 2013, the 58,677 units within the targeted programs were newly constructed or rehabilitated. However, HUD's data did not contain specific information to be able to determine how many of the units that underwent rehabilitation met the definition of "substantial rehabilitation" contained in the proposed rule, so the number of affected units would be smaller than is contained in the table. In addition, data on affected units newly constructed using CDBG funding is unavailable, as grantee reports do not separate multifamily from single-unit new construction.

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[17] *http://www.homewyse.com/services/cost_to_install_electrical_wiring.html*

TABLE III—HUD-ASSISTED NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION

	Sec. 8 RAD	811 PRAC	202 PRAC	Sec. 8 202	HOPE VI	PIH	CDBG	HOME Rental	Totals
New Construction									
2012	....	506	2,405	....	146	703			
2013	110	583	2,034	....	44	297	....	19,424	22,492
2014	100	482	1,592	....	....	....	....	11,596	
Rehabilitation									
2012	....	....	25	....	....	36			
2013	199	15	....	109	....	16	20,918	14,928	36,185
2014	....	28	15	....	....	....	15,716	6,965	
FY 2013 Totals	....	....	....	....	....	....	....	....	58,677

Further, a review found that multifamily (5-plus unit) HUD or standard-market new construction typically provides telephone landline and many provide cable TV connectivity.[18] A recent survey by the National Association of Homebuilders found that just 4 percent of the surveyed multifamily housing developers did not install landline wires and jacks in multifamily units completed in the past 12 months.[18] [19] In recent years, HUD's competitive grants for new construction under the Choice Neighborhoods program have required the provision of broadband.[20] Therefore, this proposed rule simply codifies what is considered common practice in several programs.

Accordingly, most recipients and owners already meet the standards established in the proposed rule, and the new regulatory requirements will impose minimal, if any, new economic costs. HUD has addressed those rare situations where the proposed new requirements may prove too costly by granting exceptions to the installation requirements where the installation is economically infeasible due to location or building characteristics.

The docket file is available for public inspection in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, please schedule an appointment to review the docket file by calling the Regulation Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

Impact on Small Entities

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The proposed rule would provide that for new construction or substantial rehabilitation of multifamily rental housing funded by HUD, as part of the new construction or substantial rehabilitation to be undertaken, such activity must include installation of broadband infrastructure. None of the HUD-covered programs listed in this proposed rule require a grantee to undertake new construction or substantial rehabilitation. Instead, new construction and substantial rehabilitation are eligible activities that grantees may take using HUD funds. Therefore, small entities will not incur any costs than they otherwise would incur by voluntarily undertaking new construction or substantial rehabilitation, since the costs of these activities, including the installation of broadband infrastructure, are funded by HUD. For these reasons, this proposed rule will not have a significant economic impact on a substantial number of small entities.

Notwithstanding HUD's determination that this proposed rule will not have a significant economic effect on a substantial number of small entities, HUD specifically invites comments regarding any less burdensome alternatives to this proposed rule that will meet HUD's objectives, as described in this preamble.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This proposed rule will not impose any Federal mandates on any State, local, or tribal governments or the private sector within the meaning of the UMRA.

Paperwork Reduction Act

The information collection requirements contained in this proposed rule must be submitted to OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) for review and approval. In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number.

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[18] For example under "Class 4 Low Average Quality" the Craftsman 2015 National Building Cost Manual lists cable TV as a standard feature. Only "Class 5" minimum quality does not list cable or a computer network as a standard feature. All electrical work is estimated to be 10 percent of project cost. *2015 National Building Cost Manual, supra,* p. 19.

[18] NAHB, Multifamily Market Survey, *supra.*

[19] Note that HUD's definition of accessibility is more restrictive than the FCC's because HUD considers only the building itself.

[20] United States Department of Housing and Urban Development. "Choice Neighborhoods Planning Grants Notice of Funding Availability," *supra,* p. 32. "Broadband Access. All FY2014 and FY2015 Implementation Grantees will be required, as part of their Transformation Plan, to include infrastructure that permits unit-based access to broadband Internet connectivity in all new units. Grantees may use Choice Neighborhoods funds to provide unit-based broadband Internet connectivity, which includes the costs of installing broadband infrastructure and hardware in units, but not the costs of Internet service for residents. Regular and informed Internet adoption can increase access to the job market, as well as health, education, financial and other services. Further, in-home broadband Internet access is an attractive, and in most cases, standard amenity that can be used to market the mixed-income community created through the Transformation Plan."

The burden of the information collections in this proposed rule is estimated to be minimal. The reporting of new construction or substantial rehabilitation activity under the programs covered by this proposed rule is not increased through the installation of broadband infrastructure. However, the information collection that is new is the documentation required of the grantee that the location of proposed new construction makes installation of broadband infrastructure infeasible, or that the cost of installing the infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden. The total number of grantees that undertake new construction or substantial rehabilitation, as defined in this proposed rule, with HUD funds is currently low, and this is reflected in the respondents.

REPORTING AND RECORDKEEPING BURDEN

Information collection	Number of respondents	Response frequency (average)	Burden hours per response	Total burden hours
Documentation of inability to undertake installation of broadband infrastructure	1,000	1	2	2,000
Totals	1,000	1	2	2,000

In accordance with 5 CFR 1320.8(d)(1), HUD is soliciting comments from members of the public and affected agencies concerning this collection of information to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Interested persons are invited to submit comments regarding the information collection requirements in this proposed rule. Comments must refer to the proposal by name and docket number (FR–5890–P–01) and must be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503, Fax number: 202–395–6947, and Collette Pollard, Reports Liaison Officer, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410.

Environmental Review

A Finding of No Significant Impact (FONSI) with respect to the environment has been made in accordance with HUD regulations in 24 CFR part 50 that implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The FONSI is available for public inspection, during regular business hours, in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500, or online at *www.regulations.gov.* Due to security measures at the HUD Headquarters building, please schedule an appointment to review the FONSI by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This proposed rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments nor preempt State law within the meaning of the Executive order.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers applicable to the programs that would be affected by this rule are: 14.218, 14.225, 14.228, 14.239, 14.241, 14.267, 14.850, 14.871, and 14.872.

List of Subjects

24 CFR Part 5

Administrative practice and procedure, Aged, Claims, Crime, Government contracts, Grant programs-housing and community development, Individuals with disabilities, Intergovernmental relations, Loan programs-housing and community development, Low and moderate income housing, Mortgage insurance, Penalties, Pets, Public housing, Rent subsidies, Reporting and recordkeeping requirements, Social security, Unemployment compensation, Wages.

24 CFR Part 92

Administrative practice and procedure, Low and moderate income housing, Manufactured homes, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 93

Administrative practice and procedure, Grant programs-housing and community development, Low and moderate income housing, Manufactured homes, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 570

Administrative practice and procedure, American Samoa, Community development block grants, Grant programs-education, Grant programs-housing and community development, Guam, Indians, Loan programs-housing and community development, Low and moderate income housing, Northern Mariana Islands, Pacific Islands Trust Territory, Puerto Rico, Reporting and recordkeeping requirements, Student aid, Virgin Islands.

24 CFR Part 574

Community facilities, Grant programs-housing and community development, Grant programs-social programs, HIV/AIDS, Low and moderate income housing, Reporting and recordkeeping requirements.

24 CFR Part 578

Community development, Community facilities, Grant programs-housing and community development, Grant programs-social programs, Homeless, Reporting and recordkeeping requirements.

24 CFR Part 880

Grant programs-housing and community development, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 881

Grant programs-housing and community development, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 883

Grant programs-housing and community development, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 884

Grant programs-housing and community development, Rent subsidies, Reporting and recordkeeping requirements, Rural areas.

24 CFR Part 886

Grant programs-housing and community development, Lead poisoning, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 891

Aged, Grant programs-housing and community development, Individuals with disabilities, Loan programs-housing and community development, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 905

Grant programs-housing and community development, Public housing, Reporting and recordkeeping requirements.

24 CFR Part 983

Grant programs-housing and community development, Low and moderate income housing, Rent subsidies, Reporting and recordkeeping requirements.

Accordingly, for the reasons stated in the preamble, HUD proposes to amend 24 CFR parts 5, 92, 93, 570, 574, 578, 880, 881, 883, 884, 886, 891, 905, and 983 as follows:

PART 5—GENERAL HUD PROGRAM REQUIREMENTS; WAIVERS

■ 1. The authority citation for part 5 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f, 1437n, 3535(d), Sec. 327, Pub. L. 109–115, 119 Stat. 2936, Sec. 607, Pub. L. 109–162, 119 Stat. 3051, E.O. 13279, and E.O. 13559.

■ 2. In § 5.100, add the definitions of "Broadband infrastructure" and "Substantial rehabilitation" in alphabetical order, to read as follows:

§ 5.100 Definitions.

* * * * *

Broadband infrastructure means cables, fiber optics, wiring, or other permanent (integral to the structure) infrastructure that is capable of providing access to Internet connections in individual housing units that meet the definition of "advanced telecommunications capability" determined by the Federal Communications Commission under section 706 of the Telecommunications Act of 1996 (47 U.S.C. 1302).

* * * * *

Substantial rehabilitation, for the purposes of determining when installation of broadband infrastructure is required as part of substantial rehabilitation of multifamily rental housing, unless otherwise defined by a program, means work that involves:

(1) Significant work on the electrical system of the multifamily rental housing. "Significant work" means complete replacement of the electrical system or other work that is equal to or greater than 75 percent of the cost of replacing the entire electrical system. In the case of multifamily rental housing with multiple buildings with more than 4 units, "entire system" refers to the electrical system of the building undergoing rehabilitation; or

(2) Rehabilitation of the multifamily rental housing in which the estimated cost of the rehabilitation is equal to or greater than 75 percent of the total estimated cost of replacing the multifamily rental housing after the rehabilitation is complete. In the case of multifamily rental housing with multiple buildings with more than 4 units, the replacement cost must be the replacement cost of the building undergoing rehabilitation.

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PART 92—HOME INVESTMENT PARTNERSHIPS PROGRAM

■ 3. The authority citation for part 92 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 12701–12839.

■ 4. Amend § 92.251 by revising the introductory text of (a)(2) and adding paragraphs (a)(2)(vi) and (b)(1)(x) to read as follows:

§ 92.251 Property standards.

(a) * * *

(2) *HUD requirements.* All new construction projects must also meet the requirements described in this paragraph:

* * *

(vi) *Broadband infrastructure.* If the housing is a building with more than 4 rental units, the construction must include installation of broadband infrastructure, as this term is defined in 24 CFR 5.100, except where the participating jurisdiction documents that:

(A) The location of the new construction makes installation of broadband infrastructure infeasible; or

(B) The cost of installing the infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden.

(b) * * *

(1) * * *

(x) *Broadband infrastructure.* If the housing is a building with more than 4 rental units, any substantial rehabilitation, as defined in 24 CFR 5.100, must provide for installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the participating jurisdiction documents that:

(A) The location of the substantial rehabilitation makes installation of broadband infrastructure infeasible;

(B) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(C) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

* * * * *

PART 93—HOUSING TRUST FUND

■ 5. The authority citation for part 93 continues to read as follows:

Authority: 42 U.S.C. 3535(d), 12 U.S.C. 4568.

■ 6. Amend § 93.301 by revising the introductory text of (a)(2) and adding paragraphs (a)(2)(vi) and (b)(1)(x) to read as follows:

§ 93.301 Property standards.

(a) * * *

(2) *HUD requirements.* All new construction projects must also meet the requirements described in this paragraph:

* * *

(vi) *Broadband infrastructure.* If the housing is a building with more than 4 rental units, the construction must include installation of broadband infrastructure, as this term is defined in 24 CFR 5.100, except where the grantee documents that:

(A) The location of the new construction makes installation of broadband infrastructure infeasible; or

(B) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden.

(b) * * *

(1) * * *

(x) *Broadband infrastructure.* If the housing is a building with more than 4 rental units, any substantial rehabilitation, as defined in 24 CFR 5.100, must provide for installation of broadband infrastructure, as this term is defined in 24 CFR 5.100, except where the grantee documents that:

(A) The location of the substantial rehabilitation makes installation of broadband infrastructure infeasible;

(B) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(C) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

* * * * *

PART 570—COMMUNITY DEVELOPMENT BLOCK GRANTS

■ 7. The authority citation for part 570 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 5301–5320.

■ 8. In § 570.202, add paragraph (g) to read as follows:

§ 570.202 Eligible rehabilitation and preservation activities.

* * * * *

(g) *Broadband infrastructure.* Any substantial rehabilitation, as defined by 24 CFR 5.100, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the grantee documents that:

(1) The location of the substantial rehabilitation makes installation of broadband infrastructure infeasible;

(2) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(3) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

■ 9. In § 570.204 add paragraph (a)(5) to read as follows:

§ 570.204 Special activities by Community-Based Development Organizations (CBDOs).

(a) * * *

(5) Any new construction or substantial rehabilitation, as defined by 24 CFR 5.100, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the grantee documents that:

(i) The location of the new construction or substantial rehabilitation makes installation of broadband infrastructure infeasible;

(ii) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(iii) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

* * * * *

■ 10. Add paragraph (c)(4) to § 570.482 to read as follows:

§ 570.482 Eligible activities.

* * * * *

(c) * * *

(4) *Broadband infrastructure in housing.* Any new construction or substantial rehabilitation, as defined by 24 CFR 5.100, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the State documents that:

(i) The location of the new construction or substantial rehabilitation makes installation of broadband infrastructure infeasible;

(ii) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(iii) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

* * * * *

PART 574—HOUSING OPPORTUNITIES FOR PERSONS WITH AIDS

■ 11. The authority citation for part 574 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 12901–12912.

■ 12. Add § 574.350 to subpart D to read as follows:

§ 574.350 Additional standards for broadband infrastructure.

Any new construction or substantial rehabilitation, as substantial rehabilitation is defined by 24 CFR 574.3, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is defined in 24 CFR 5.100, except where the grantee documents that:

(1) The location of the new construction or substantial rehabilitation makes installation of broadband infrastructure infeasible;

(2) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(3) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

PART 578—CONTINUUM OF CARE PROGRAM

■ 13. The authority citation for part 578 continues to read as follows:

Authority: 42 U.S.C. 11371 *et seq.*, 42 U.S.C. 3535(d).

■ 14. In § 578.45, add paragraph (d) to read as follows:

§ 578.45 Rehabilitation.

* * * * *

(d) *Broadband infrastructure.* Any substantial rehabilitation, as defined by 24 CFR 5.100, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the grantee documents that:

(1) The location of the substantial rehabilitation makes installation of broadband infrastructure infeasible;

(2) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(3) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

■ 15. In § 578.47, add paragraph (c) to read as follows:

§ 578.47 New construction.

* * * * *

(c) *Broadband infrastructure.* Any new construction of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is defined in 24 CFR 5.100, except where the grantee documents that:

(1) The location of the new construction makes installation of broadband infrastructure infeasible; or

(2) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden.

PART 880—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM FOR NEW CONSTRUCTION

■ 16. The authority citation for part 880 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f, 3535(d), 12701, and 13611–13619.

■ 17. Add § 880.212 to subpart B to read as follows:

§ 880.212 Broadband infrastructure.

Any new construction or substantial rehabilitation, as defined by 24 CFR 5.100, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the owner documents that:

(1) The location of the new construction or substantial rehabilitation makes installation of broadband infrastructure infeasible;

(2) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(3) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

PART 881—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM FOR SUBSTANTIAL REHABILITATION

■ 18. The authority citation for part 881 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f, 3535(d), 12701, and 13611–13619.

■ 19. Add § 881.212 to subpart B to read as follows:

§ 881.212 Broadband infrastructure.

Any new construction or substantial rehabilitation, as defined by 24 CFR 5.100, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the owner documents that:

(1) The location of the new construction or substantial rehabilitation makes installation of broadband infrastructure infeasible;

(2) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(3) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

PART 883—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM—STATE HOUSING AGENCIES

■ 20. The authority citation for part 883 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f, 3535(d), and 13611–13619.

■ 21. Add § 883.314 to subpart C to read as follows:

§ 883.314 Broadband infrastructure.

Any new construction or substantial rehabilitation, as defined by 24 CFR 5.100, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the owner documents that:

(1) The location of the new construction or substantial rehabilitation makes installation of broadband infrastructure infeasible;

(2) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(3) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

PART 884—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM, NEW CONSTRUCTION SET-ASIDE FOR SECTION 515 RURAL RENTAL HOUSING PROJECTS

■ 22. The authority citation for part 884 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f, 3535(d), and 13611–13619.

■ 23. Add § 884.125 to subpart A to read as follows:

§ 884.125 Broadband infrastructure.

Any new construction or substantial rehabilitation, as defined by 24 CFR 5.100, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the owner documents that:

(1) The location of the new construction or substantial rehabilitation makes installation of broadband infrastructure infeasible;

(2) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(3) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

PART 886—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM—SPECIAL ALLOCATIONS

■ 24. The authority citation for part 886 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f, 3535(d), and 13611–13619.

■ 25. Add § 886.139 to subpart A to read as follows:

§ 886.139 Broadband infrastructure.

Any new construction or substantial rehabilitation, as defined by 24 CFR 5.100, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the owner documents that:

(1) The location of the new construction or substantial rehabilitation makes installation of broadband infrastructure infeasible;

(2) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(3) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

■ 26. Add § 886.339 to subpart C to read as follows:

§ 886.339 Broadband infrastructure.

Any new construction or substantial rehabilitation, as defined by 24 CFR 5.100, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the owner documents that:

(1) The location of the new construction or substantial rehabilitation makes installation of broadband infrastructure infeasible;

(2) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(3) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

PART 891—SUPPORTIVE HOUSING FOR THE ELDERLY AND PERSONS WITH DISABILITIES

■ 27. The authority citation for part 891 continues to read as follows:

Authority: 12 U.S.C. 1701q; 42 U.S.C. 1437f, 3535(d), and 8013.

■ 28. In § 891.120, add paragraph (f) to read as follows:

§ 891.120 Project design and cost standards.

* * * * *

(f) *Broadband infrastructure.* Any new construction or substantial rehabilitation, as defined by 24 CFR 5.100, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the owner documents that:

(1) The location of the new construction or substantial rehabilitation makes installation of broadband infrastructure infeasible;

(2) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(3) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

■ 29. Add § 891.550 to subpart E to read as follows:

§ 891.550 Broadband infrastructure.

Any new construction or substantial rehabilitation, as defined by 24 CFR 5.100, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the owner documents that:

(1) The location of the new construction or substantial rehabilitation makes installation of broadband infrastructure infeasible;

(2) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(3) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

PART 905—THE PUBLIC HOUSING CAPITAL FUND PROGRAM

■ 30. The authority citation for part 905 continues to read as follows:

Authority: 42 U.S.C. 1437g, 42 U.S.C. 1437z-2, 42 U.S.C. 1437z-7, and 3535(d).

■ 31. In § 905.312, add paragraph (e) to read as follows:

§ 905.312 Design and construction.

* * * * *

(e) *Broadband infrastructure.* Any new construction or substantial rehabilitation, as defined in 24 CFR 5.100, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the PHA documents that:

(1) The location of the new construction or substantial rehabilitation makes installation of broadband infrastructure infeasible;

(2) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(3) The structure of the housing to be rehabilitated makes installation of broadband infrastructure infeasible.

PART 983—PROJECT–BASED VOUCHER (PBV) PROGRAM

■ 32. The authority citation for part 983 continues to read as follows:

Authority: 42 U.S.C. 1437f and 3535(d).

■ 33. Add § 983.157 to subpart D to read as follows:

§ 983.157 Broadband infrastructure.

Any new construction or substantial rehabilitation, as defined by 24 CFR 5.100, of a building with more than 4 rental units must include installation of broadband infrastructure, as this term is also defined in 24 CFR 5.100, except where the owner documents that:

(1) The location of the new construction or substantial rehabilitation makes installation of broadband infrastructure infeasible;

(2) The cost of installing broadband infrastructure would result in a fundamental alteration in the nature of its program or activity or in an undue financial burden; or

(3) The structure of the housing to be substantially rehabilitated makes installation of broadband infrastructure infeasible.

Dated: April 21, 2016.

Julián Castro,

Secretary.

[FR Doc. 2016–11352 Filed 5–17–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 91

[Docket No. FR 5891–P–01]

RIN 2506–AC41

Modernizing HUD's Consolidated Planning Process To Narrow the Digital Divide and Increase Resilience to Natural Hazards

AGENCY: Office of the Assistant Secretary for Community Planning and Development, Department of Housing and Urban Development.

ACTION: Proposed rule.

SUMMARY: HUD's Consolidated Plan is a planning mechanism designed to help States and local governments to assess their affordable housing and community development needs and to make data-driven, place-based investment decisions. The consolidated planning process serves as the framework for a community-wide dialogue to identify housing and community development priorities that align and focus funding from HUD's formula block grant programs. This proposed rule would amend HUD's Consolidated Plan regulations to require that jurisdictions consider two additional concepts in their planning efforts.

The first concept is how to address the need for broadband access for low- and moderate-income residents in the communities they serve. Broadband is the common term used to refer to a high-speed, always on connection to the Internet. Such connection is also referred to as high-speed broadband or high-speed Internet. Specifically, the proposed rule would require that States and localities that submit a consolidated plan describe the broadband access in housing occupied by low- and moderate-income households. If low-income residents in the communities do not have such access, States and jurisdictions must consider providing broadband access to these residents into their decisions on how to invest HUD funds. The second concept to be added to the Consolidated Plan process would require jurisdictions to consider incorporating resilience to natural hazard risks, taking care to anticipate how risks will increase due to climate change, into development of the Plan in order to begin addressing impacts of climate change on low- and moderate-income residents.

DATES: *Comments Due Date:* July 18, 2016.

ADDRESSES: Interested persons are invited to submit comments responsive to this proposed rule to the Office of General Counsel, Regulations Division, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0001. All submissions should refer to the above docket number and title. Submission of public comments may be carried out by hard copy or electronic submission.

1. *Submission of Hard Copy Comments.* Comments may be submitted by mail or hand delivery. Each commenter submitting hard copy comments, by mail or hand delivery, should submit comments to the address above, addressed to the attention of the

Regulations Division. Due to security measures at all federal agencies, submission of comments by mail often results in delayed delivery. To ensure timely receipt of comments, HUD recommends that any comments submitted by mail be submitted at least 2 weeks in advance of the public comment deadline. All hard copy comments received by mail or hand delivery are a part of the public record and will be posted to *http://www.regulations.gov* without change.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make comments immediately available to the public. Comments submitted electronically through the *http://www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow instructions provided on that site to submit comments electronically.

No Facsimile Comments. Facsimile (fax) comments are not acceptable.

Public Inspection of Comments. All comments submitted to HUD regarding this rule will be available, without charge, for public inspection and copying between 8 a.m. and 5 p.m., Eastern Time, weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number through TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number). Copies of all comments submitted are available for inspection and downloading at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Lora Routt, Senior Advisor, Office of Community Planning and Development, Department of Housing and Urban Development, Office of Community Planning and Development, 451 7th Street SW., Suite 7204, Washington, DC 20410 at 202–402–4492, (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service, toll-free, at 800–877–8339.

Persons with hearing or speech impairments may access this number through TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of This Proposed Rule

The purpose of this proposed rule is to require States and local governments to evaluate the availability of broadband access and the vulnerability of housing occupied by low- and moderate income households to natural hazard risks, many of which may be increasing due to climate change, in their consolidated planning efforts. These evaluations will be conducted using readily available data sources developed by Federal government agencies and other available data and analyses, including State, Tribal, and local hazard mitigation plans that have been approved by the Federal Emergency Management Agency (FEMA). Where access to broadband Internet service is not currently available or is minimally available (such as in certain rural areas), States and local governments must consider ways to bring broadband Internet access to low- and moderate-income residents, including how HUD funds could be used to narrow the digital divide for these residents. Further, where low- and moderate-income communities are at risk of natural hazards, including those that are expected to increase due to climate change, States and local governments must consider ways to incorporate appropriate hazard mitigation and resilience into their community planning and development goals, codes, and standards, including the use of HUD funds. These two planning considerations reflect emerging needs of communities in this changing world. Broadband access provides access to a wide range of resources, services, and products and such access not only can assist individuals in improving their economic outlook, but also assists communities in this same way. Analysis of natural hazards, including the anticipated effects of climate change on those hazards, is important to help ensure that jurisdictions are aware of existing and developing vulnerabilities in the geographic areas that they serve that can threaten the health and safety of the populations they serve.

B. Summary of Major Provisions of This Proposed Rule

The current regulations require that local governments and States consult public and private agencies that provide assisted housing, health services, and social and fair housing services during preparation of the consolidated plan. Under the current regulations, local governments and States are also required in their citizen participation plan to encourage the participation of local and regional institutions and businesses in the process of developing and implementing their consolidated plans. The proposed rule would require States and local governments, in preparing their consolidated plans, to add to the list of public and private agencies and entities that they now must consult with for preparation of their plans, to consult with public and private organizations, including broadband Internet service providers, organizations engaged in narrowing the digital divide (*e.g.*, schools, digital literacy organizations), and agencies whose primary responsibilities include the management of floodprone areas, public land or water resources, and emergency management agencies. Jurisdictions must also encourage the participation of these entities in implementing relevant components of the plan.

The proposed rule would also require jurisdictions to describe broadband access in housing occupied by low- and moderate-income households based on an analysis of data for its low- and moderate-income neighborhoods in the National Broadband Map[1] created by the National Telecommunications and Information Administration (NTIA) of the Department of Commerce. Grantees may also use broadband availability data in the Federal Communications Commission (FCC) Form 477[2] or other data identified by the jurisdiction, for which the source is cited in the jurisdiction's Consolidated Plan. These needs include the need for broadband wiring and for connection to the broadband service in the household units, the need for increased competition by having more than one broadband Internet service provider serve the jurisdiction.

The proposed rule would also require that jurisdictions provide, as part of their required housing market analysis, an assessment of natural hazard risks, including risks expected to increase due to climate change, to low- and moderate-income residents based on an analysis of data, findings, and methods in (1) the most recent National Climate

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[1] See *http://www.broadbandmap.gov.*

[2] See *https://www.fcc.gov/general/broadband-deployment-data-fcc-form-477.*

Assessment,[3] the Climate Resilience Toolkit,[4] the Impact of Climate Change and Population Growth on the National Flood Insurance Program Through 2100,[5] or the Community Resilience Planning Guide for Buildings and Infrastructure Systems prepared by the National Institute of Standards and Technology (NIST);[6] (2) other climate risk-related data published by the Federal government or other State or local government climate risk related data, including FEMA-approved hazard mitigation plans which incorporate climate change; or (3) other climate risk data identified by the jurisdiction, for which the source is cited in the jurisdiction's Consolidated Plan. Grantees may request Technical Assistance through their HUD Field Office or directly at *www.HUDExchange.info/get-assistance*.

C. Costs and Benefits of This Proposed Rule

HUD's Consolidated Plan process, established by regulation in 1994, provides a comprehensive planning process for HUD programs administered by HUD's Office of Community Planning and Development, specifically the Community Development Block Grant (CDBG) program, the HOME Investment Partnerships (HOME) program, Emergency Solutions Grants (ESG) program and the Housing with Opportunities for Persons With AIDS (HOPWA). Comprehensive community planning provides officials with an informative profile of their communities in terms of population, housing, economic base, community facilities, and transportation systems, and such information aids officials in their investment decisions. HUD's Consolidated Planning process assists State and local officials that are recipients of HUD funds under the above-listed programs in determining the housing and community development needs of their respective communities. Requiring consolidated plan jurisdictions to consider the broadband and natural hazard resilience needs of their communities helps to ensure a more complete profile of the needs of their communities. As discussed in this preamble, the importance of providing broadband access to all cannot be overstated. Broadband access is not only important to increasing opportunity for an individual's success, but to the success of a community. Consideration of the impact of natural hazard risks, many of which are anticipated to increase due to climate change, in one's community, and how communities can help mitigate any such adverse impacts, is equally important as it will help to guide the best use of land and orderly and sustainable growth. In brief, the benefits of this proposed rule are to promote a balanced planning process that more fully considers the housing, environmental, and economic needs of communities.

HUD does not anticipate that the costs of the revised consultation and reporting requirements will be significant since the regulatory changes proposed by this proposed rule merely build upon similar existing requirements for other elements covered by the consolidated planning process rather than mandating completely new procedures. Further, the required assessments will be based on data readily available on the Internet. Therefore, jurisdictions will not have to incur the expense and administrative burdens associated with collecting data. Moreover, this proposed rule does not mandate that actions be taken to address broadband needs or climate change adaptation needs. Consolidated plan jurisdictions are in the best position to decide how to expend their HUD funds. However, HUD believes that the additional analyses required by this rule may highlight areas where expenditure of funds would assist in opening up economic opportunities through increased broadband access or mitigate the impact of possible natural hazards, including those that may be exacerbated due to climate change. HUD leaves it to jurisdictions to consider any appropriate methods to promote broadband access or protect against the adverse impacts of climate change, taking into account the other needs of their communities, and available funding, as identified through the consolidated planning process.

II. Background

A. Broadband

On March 23, 2015, President Obama issued a Presidential Memorandum on "Expanding Broadband Deployment and Adoption by Addressing Regulatory Barriers and Encouraging Investment and Training."[7] In this memorandum, the President noted that access to high-speed broadband is no longer a luxury, but it is a necessity for American families, businesses, and consumers.[8] The President further noted that the Federal government has an important role to play in developing coordinated policies to promote broadband deployment and adoption, including promoting best practices, breaking down regulatory barriers, and encouraging further investment.

The memorandum established an interagency Broadband Opportunity Council, including representatives from the Executive Branch agencies, for the purposes of consulting with State, local, tribal, and territorial governments, as well as telecommunications companies, utilities, trade associations, philanthropic entities, policy experts, and other interested parties to identify and assess regulatory barriers and opportunities to broadband adoption. The council's report, published by the White House on September 21, 2015, included a number of specific actions that agencies (including HUD) agreed to take to promote greater broadband deployment and adoption. This change to the Consolidated Planning process is one of those actions.[9]

On July 15, 2015, HUD launched its Digital Opportunity Demonstration, known as "ConnectHome," in which HUD provided a platform for collaboration among local governments, public housing agencies, Internet service providers, philanthropic foundations, nonprofit organizations and other relevant stakeholders to work together to produce local solutions for narrowing the digital divide in communities across the nation served by HUD.[10] The demonstration, or pilot as it is also called, commenced with the participation of 28 communities. Through contributions made by the Internet service providers and other organizations participating in the pilot, these 28 communities will benefit from the ConnectHome collaboration by receiving, for the residents living in HUD public and assisted housing in these communities, broadband infrastructure, technical assistance, literacy training, and electronic devices that provide for accessing high-speed Internet.

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[3] See *http://nca2014.globalchange.gov/highlights#submenu-highlights-overview*.

[4] See *https://toolkit.climate.gov*.

[5] See *http://www.acclimatise.uk.com/login/uploaded/resources/FEMA_NFIP_report.pdf*.

[6] See *http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1197.pdf*.

[7] See *https://www.whitehouse.gov/the-press-office/2015/03/23/presidential-memorandum-expanding-broadband-deployment-and-adoption-addr*.

[8] The Web page for the National Broadband Map explains that "broadband refers to a high-speed, always-on connection to the Internet. The primary factors that people consider when deciding what type of broadband Internet service to subscribe to include service availability, connection speed, technology and price. Organizations define broadband in different ways. For information to be included on the National Broadband Map, the technology must provide a two-way data transmission (to and from the Internet) with advertised speeds of at least 768 kilobits per second (kbps) downstream and at least 200 kbps upstream to end users." Please see *http://www.broadbandmap.gov/*.

[9] See, Broadband Opportunity Council, Report to President Obama at p. 14 (Aug. 20, 2015), available at *https://www.whitehouse.gov/sites/default/files/broadband_opportunity_council_report_final.pdf*.

[10] See *https://www.whitehouse.gov/the-press-office/2015/07/15/fact-sheet-connecthome-coming-together-ensure-digital-opportunity-all*.

On March 9, 2016, President Obama launched the ConnectALL initiative to ensure that more Americans have the broadband they need to get a job, engage their community, and deliver opportunity to their children.[11] ConnectALL will increase the affordability of broadband for low-income Americans; deliver digital literacy skills; increase access to affordable devices; develop a tool to support broadband planning; bring together private sector corporations helping to deliver affordable connectivity; and marshal philanthropic support for digital inclusion. The goal of ConnectALL is to create a national effort to connect 20 million more Americans to broadband by 2020.

The importance of all Americans having access to the Internet cannot be overstated. As HUD stated in its announcement of the Digital Opportunity Demonstration, published in the **Federal Register** on April 3, 2015, at 80 FR 18248, "[k]nowledge is a pillar to achieving the American Dream—a catalyst for upward mobility as well as an investment that ensures each generation is as successful as the last." [12] Many low-income Americans do not have broadband Internet at home, contributing to the estimated 66 million Americans who are without the most basic digital literacy skills. Without broadband access and connectivity and the skills to use Internet technology at home, children will miss out on the high-value educational, economic, and social impact that high-speed Internet provides. It is for these reasons that HUD is exploring ways, beyond ConnectHome, to narrow the digital divide for the low-income individuals and families served by HUD multifamily rental housing programs. This proposed rule presents one such additional effort.

B. Natural Hazards Resilience

On November 1, 2013, President Obama signed Executive Order 13653, on "Preparing the United States for the Impacts of Climate Change." [13] The Executive Order recognizes that the impacts of climate change—including an increase in prolonged periods of excessively high temperatures, more heavy downpours, an increase in wildfires, more severe droughts, permafrost thawing, ocean acidification, and sea-level rise—are often most significant for communities that already face economic or health-related challenges. Research has developed the concept of social vulnerability, which describes characteristics (age, gender, socioeconomic status, special needs, race, and ethnicity) of populations that influence their capacity to prepare for, respond to, and recover from hazards and disasters, including the sensitivity of a population to climate change impacts and how different people or groups are more or less vulnerable to those impacts. Social vulnerability and equity in the context of climate change are important because some populations may have less capacity to prepare for, respond to, and recover from climate-related hazards and effects.[14] Executive Order 13653 asserts that managing these risks requires deliberate preparation, close cooperation, and coordinated planning by the federal government, State, Tribal, and local governments, and stakeholders. Further, the Executive Order calls upon Federal agencies to identify opportunities to support and encourage smarter, more climate-resilient investments by States, local communities, and tribes, through grants and other programs, in the context of infrastructure development.

Section 7 of Executive Order 13653 established the President's State, Local, and Tribal Leaders Task Force on Climate Change Resilience and Preparedness (Task Force). Co-chaired by the Chair of the White House Council on Environmental Quality and the Director of the White House Office of Intergovernmental Affairs, the Task Force consisted of 26 governors, mayors, county officials, and Tribal leaders from across the United States. Members brought first-hand experiences in building climate preparedness and resilience in their communities and conducted broad outreach to thousands of government agencies, trade associations, planning agencies, academic institutions, and other stakeholders, to inform their recommendations to the Administration.

The President charged the Task Force with providing recommendations on how the Federal government can respond to the needs of communities nationwide that are dealing with the impacts of climate change by removing barriers to resilient investments, modernizing Federal grant and loan programs to better support local efforts, and developing the information and tools they need to prepare, among other measures. In November 2014, Task Force members presented their recommendations for the President at a White House meeting with Vice President Biden and other senior Administration officials.[15] Among other actions, the Task Force called on HUD to consider strategies within existing grant programs to facilitate and encourage integrated hazard mitigation approaches that address climate-change related risks, land use, development codes and standards, and capital improvement planning. This proposed rule represents one step that HUD is taking to implement these recommendations.

III. This Proposed Rule

HUD's consolidated planning process serves as the framework for a community-wide dialogue to identify housing and community development priorities that align and focus funding from the HUD formula block grant programs: Community Development Block Grant (CDBG) program, HOME Investment Partnerships (HOME) program, Emergency Solutions Grant (ESG) program, and Housing Opportunities for Persons With AIDS (HOPWA) program. HUD's regulations for the consolidated planning are codified at 24 CFR part 91(entitled "Consolidated Submissions for Community Planning and Development Programs").

The Consolidated Plan, which may have a planning duration of between 3 and 5 years, is designed to help States and local governments assess their affordable housing and community development needs, in the context of market conditions at the time of their planning, and to make data-driven, place-based decisions on how to expend HUD funds in their jurisdictions. In developing their consolidated plans, States and local governments are required to engage their communities, both in the process of developing and reviewing the proposed plan, and as partners and stakeholders in the implementation of the plan. By consulting and collaborating with other public and private entities, States and local governments can better align and coordinate community development programs with a range of other plans, programs, and resources to achieve greater impact. A jurisdiction's consolidated plan is carried out through annual action plans, which provide a concise summary of the actions, activities, and the specific Federal and non-federal resources that will be used each year to address the priority needs and specific goals identified by the Consolidated Plan. States and local governments report on accomplishments and progress toward consolidated plan goals in the Consolidated Annual Performance and Evaluation Report (CAPER).

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[11] *https://www.whitehouse.gov/the-press-office/2016/03/09/fact-sheet-president-obama-announces-connectall-initiative.*

[12] 80 FR18248, at 18249.

[13] Executive Order 13653 was subsequently published in the **Federal Register** on November 6, 2013, at 78 FR 66819.

[14] A summary of research on social vulnerability is provided in Kathy Lynn, Katharine MacKendrick, and Ellen M. Donoghue, *Social Vulnerability and Climate Change: Synthesis of Literature* (United States Department of Agriculture, August 2011), available online at: *http://www.fs.fed.us/pnw/pubs/pnw_gtr838.pdf.*

[15] *https://www.whitehouse.gov/administration/eop/ceq/initiatives/resilience/taskforce.*

The regulatory amendments proposed by this rule would require States and local governments to consider broadband access and natural hazard resilience as part of their consolidated planning efforts. As provided in this proposed rule, States and local governments will need to consider the broadband needs of their low- and moderate-income residents, and the extent that available broadband Internet service providers and technology support these residents' broadband access needs. Where the required analysis demonstrates that such support is not currently available or is minimally available, States and local governments should consider ways to bring broadband Internet access to these residents, such as the extent to which broadband Internet service providers could be solicited to contribute to the broadband access needs of low-income residents, or how HUD funds could be used to narrow the digital divide for low- and moderate-income residents.

Further, where the required analysis demonstrates that low- and moderate-income communities are at risk of natural hazards, including those that may be exacerbated due to climate change, States and local governments should consider ways to incorporate hazard mitigation and resilience into their community planning and development goals, development codes, and standards, including how HUD funds could be used to mitigate natural hazard risks, including increasing risks due to climate change, with other Federal, State, local, philanthropic, and private sector funding. In this regard, President Obama's Administration is committed to giving communities across the United States the information and tools they need to plan for current and future climate change impacts, such as flooding and sea-level rise. In March 2014, the Administration launched the Climate Data Initiative, an effort to make vast Federal data resources on climate change risks and impacts openly available to the public.[16] Following a major disaster designation, jurisdictions should consider reviewing and possibly revising the required resilience analysis. Such a review would assist jurisdictions in determining whether the disaster has introduced new or unanticipated hazard risks and consequences or unmet needs. Such a review would assist jurisdictions in deciding how best to use HUD funds to address new resilience-related and disaster recovery-related needs. HUD specifically invites public comments on the need for this type of post-disaster review and the possibility of requiring such a reevaluation at the final rule stage.

This proposed rule is one part of a broader set of Administration and HUD initiatives to narrow the digital divide and enhance climate resilience in low-income communities. Given the focus of the consolidated plan on housing needs, the assessments required by the proposed rule are limited to broadband access in housing and the vulnerability of housing to natural hazard risks. HUD, however, is cognizant of the critical non-housing needs of low-income communities. The adoption of broadband, which includes digital literacy by low-income residents is an equally critical component of closing the digital divide. Likewise, the evaluation of vulnerability to natural hazard risks on a broader, community-wide, level is an equally significant component of ensuring the resilience of low-income households. Under 24 CFR 91.215 (for local governments) and 24 CFR 92.315 (for States), jurisdictions must provide a description of priority non-housing community development needs eligible for assistance under HUD's community development programs. Given the importance of broadband adoption to communities and the goals of this rulemaking, HUD strongly encourages jurisdictions to consider implementing such actions in their non-housing community development efforts. Similarly, HUD strongly encourages jurisdictions to consider the use of block grant funds for actions that enhance the resilience of communities to natural hazard risks as a whole. To this end, jurisdictions should consider basing such actions on the FEMA-approved State, Tribal, and local hazard mitigation plans that may be used to conduct the housing-specific assessments required by the proposed rule.

In addition, HUD continues to encourage regional planning considerations, and maintains the requirement for local governments and States to, in their citizen participation plan, encourage the participation of local and regional institutions and businesses in the process of developing and implementing their consolidated plans.

The proposed rule would make the following changes to the Consolidated Plan regulations:

1. *Consultation and citizen participation requirements (§§ 91.100.91.105. 91.110, 91.115).* The current regulations require that local governments and States consult public and private agencies that provide assisted housing, health services, and social and fair housing services during preparation of the consolidated plan. Under the current regulations, local governments and States are also required, in their citizen participation plan, to encourage the participation of local and regional institutions and businesses in the process of developing and implementing their consolidated plans. The proposed rule would amend these requirements to specify that local governments and States must consult with public and private organizations, including broadband Internet service providers, and other organizations engaged in narrowing the digital divide. Further, the citizen participation plan must encourage their participation in implementing any components of the plan designed to narrow the digital divide for low-income residents. The proposed rule would also require local governments and States to consult with agencies whose primary responsibilities include the management of floodprone areas, public land or water resources, and emergency management agencies in the process of developing the consolidated plan.

2. *Contents of Consolidated Plan (§§ 91.5, 91.200, 9.200, 91.210, 91.300, 91.310).* The proposed rule would make several changes to subparts C and D of HUD's regulations 24 CFR part 91, which establish the required contents of the consolidated plan. First, the proposed rule would require that, in describing their consultation efforts, local governments and States describe their consultations with public and private organizations, including broadband Internet service providers, other organizations engaged in narrowing the digital divide, agencies whose primary responsibilities include the management of floodprone areas, public land or water resources, and emergency management agencies.

Second, the jurisdiction must also describe broadband needs in housing occupied by low- and moderate-income households based on an analysis of data for its low- and moderate-income neighborhoods in the National Broadband Map. The National Broadband Map Web site may be accessed at *http://www.broadbandmap.gov/*. Grantees may also use broadband availability data in the FCC Form 477 or other data identified by the jurisdiction, for which the source is cited in the jurisdiction's Consolidated Plan. These needs include the need for broadband wiring and for connection to the broadband service in the household units, the need for increased competition by having more than one broadband Internet service provider serve the jurisdiction.

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[16] See *http://www.data.gov/climate/*.

Third, the proposed rule would also require the jurisdiction to provide an assessment of natural hazard risk to low- and moderate-income residents based on an analysis of data, findings and methods in (1) the most recent National Climate Assessment, the Climate Resilience Toolkit, the Impact of Climate Change and Population Growth on the National Flood Insurance Program Through 2100, or the Community Resilience Planning Guide for Buildings and Infrastructure Systems prepared by the National Institute of Standards and Technology (NIST); (2) other climate risk-related data published by the Federal government or other State or local government climate risk related data, including FEMA-approved hazard mitigation plans which incorporate climate change; or (3) other climate risk data identified by the jurisdiction, for which the source is cited in the jurisdiction's Consolidated Plan.

The National Climate Assessment, located at *http://nca2014.globalchange.gov/*, summarizes the impacts of climate change on the United States, now and in the future. A team of more than 300 experts guided by a 60-member Federal Advisory Committee produced the report, which was extensively reviewed by the public and experts, including federal agencies and a panel of the National Academy of Sciences.[17]

The Climate Resilience Toolkit, located at *http://toolkit.climate.gov* provides science-based tools, information, and expertise to help people manage their climate-related risks and opportunities, and improve their resilience to extreme events. The site is designed to serve interested citizens, communities, businesses, resource managers, planners, and policy leaders at all levels of government. The Climate Resilience Toolkit was developed over a six-month period in 2014 by a partnership of federal agencies and organizations led by National Oceanic and Atmospheric Administration.[18]

FEMA sponsored the report on Impact of Climate Change and Population Growth on the National Flood Insurance Program (available at *http://www.acclimatise.uk.com/login/uploaded/resources/FEMA_NFIP_report.pdf*) to fulfill a recommendation made by the Government Accountability Office to analyze the potential long-term implications of climate change and population growth on the National Flood Insurance Program. The study addresses riverine and coastal flood response to climate change, with projections at 20-year intervals through 2100, and found that the national average increase in floodprone areas by the year 2100 may approximate 40–45% for riverine areas and coastal areas.

The National Institute of Standards and Technology's (NIST) Community Resilience Planning Guide for Buildings and Infrastructure Systems, located at *http://www.nist.gov/el/resilience*, provides a six-step planning process that towns, cities, and counties can apply to better withstand hazard events and recovery more quickly. It provides a practical approach to help communities set priorities, allocate resources, and adopt codes and standards to reduce natural hazard and climate change risks by improving their resilience.

By undertaking these two analyses as part of their consolidated planning, HUD believes that jurisdictions become better informed of two emerging community needs in the world today: (1) The importance of broadband access, which opens up opportunity to a wide range of services, markets, jobs, educational, cultural and recreational opportunities; and (2) the importance of being cognizant and prepared for environmental and geographical conditions that may threaten the health and safety of communities. As noted earlier in this preamble, HUD is not mandating that jurisdictions take actions in either of these areas, but HUD believes that these are two areas that must be taken into consideration in a jurisdiction's planning for its expenditure of HUD funds.

IV. Findings and Certifications

Regulatory Review—Executive Orders 12866 and 13563

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory Review) directs executive agencies to analyze regulations that are "outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. This rule was determined to be a "significant regulatory action" as defined in section 3(f) of Executive Order (although not an economically significant regulatory action, as provided under section 3(f)(1) of the Executive Order).

As noted in this preamble, the proposed regulatory amendments are designed to assist Consolidated Plan jurisdictions assess two emerging needs of communities in this changing world. Specifically, the proposed rule will direct States and local governments to consider broadband access and natural hazard resilience in their consolidated planning efforts by using readily available online data sources. Where access to broadband Internet service is either not currently available or only minimally available, jurisdictions will be required to consider ways to bring broadband Internet access to low- and moderate-income residents, including how HUD funds could be used to narrow the digital divide for these residents. Further, where low- and moderate-income communities are at risk of natural hazards, including those that may be exacerbated due to climate change, States and local governments must consider ways to incorporate hazard mitigation and resilience into their community planning and development goals, including the use of HUD funds.

Benefits and Costs of the Proposed Rule

A. Benefits

The Consolidated Planning process benefits jurisdictions by establishing the framework for a community-wide dialogue to identify housing and community development needs for over a thousand communities across the Nation.[19] Rather than a piecemeal approach to planning based on differing program requirements, the Consolidated Plan enables a holistic approach to the assessment of affordable housing and community development needs and market conditions. HUD established the Consolidated Plan, through a 1994 final rule, for the explicit purpose of linking disparate program planning requirements, thereby ensuring "that the needs and resources of . . . [jurisdictions] are included in a comprehensive planning effort to revitalize distressed neighborhoods and help low-income residents locally." [20] The Consolidated Plan replaced a dozen separate planning mechanisms with a unified approach enabling communities to make data-driven, place-based investment decisions.[21]

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[17] *http://nca2014.globalchange.gov/*.

[18] *https://toolkit.climate.gov/content/about-climate-resilience-toolkit*.

[19] The Consolidated Plan is used by 1,255 jurisdictions. This number includes 1,205 localities all 50 States.

New housing and community development needs have arisen in the 21 years since the Consolidated Plan was created. As noted in this preamble, two of the most pressing emerging needs facing communities in the twenty-first century are the digital divide and climate change:

- In a recent analysis, the President's Council of Economic Advisers (CEA) noted that the benefits of broadband Internet technology have not been evenly distributed.[22] Research shows that there remain substantial disparities in both Internet use and the quality of access. This "digital divide" is concentrated among older, less educated, and less affluent populations, as well as in rural parts of the country that tend to have fewer choices and slower connections.[23]
- As President Obama has noted, climate change is happening now; it is not a distant threat. Its effects are already being felt in communities across the Nation. In some regions, droughts, wildfires, and floods are becoming more frequent and/or intense.[24] Average temperatures across the United States have increased between 1.3 and 1.9 degrees Fahrenheit since recordkeeping began in 1895.[25] Heat waves, hurricanes, and severe storms have all become more intense, and sea level rise is causing some communities to flood at high tides and threatening homes and critical infrastructure. Climate impacts have affected every region across the nation and inflicted large costs on the economy.[26]

Despite the benefits described above of a comprehensive approach to planning and the allocation of scarce Federal dollars, jurisdictions are not currently required to consider either the digital divide or climate change resilience in development of their Consolidated Plans. Jurisdictions may therefore place a low priority on assessing, and using Federal dollars to address, these critical issues than on other needs included in the Consolidated Plan. As a worst case scenario, it could mean that communities elect to defer considering these needs.

The direct benefits provided by the proposed rule are, therefore, to help ensure that Consolidated Plan jurisdictions consider broadband access and natural hazard resilience as part of their comprehensive assessment and planning efforts, including the most effective use of HUD grant funds. The CEA broadband analysis discussed above noted that closing the digital divide can increase productivity and open ladders of opportunity. Likewise, community investment in natural hazard resilience may help to insure security and quality of life against the rising environmental tolls associated with climate change.[27]

B. Costs

HUD does not anticipate that the costs of the revised consultation and reporting requirements will be substantial since the regulatory changes proposed by this proposed rule merely build upon similar existing requirements for other elements covered by the consolidated planning process rather than mandating completely new procedures. The economic costs of completing the Consolidated Plan are not significant. A complete Consolidated Plan that contains both a Strategic Plan and Annual Action Plan is submitted once every 3 to 5 years. An Annual Action Plan is submitted once a year. HUD data indicate that the cost of preparing the Strategic Plan for a locality is $5,236, and for a State is $14,382. The cost of preparing the Annual Action Plan is $1,904 for a locality and $6,392 for each State. While these are not trivial amounts, they are not substantial when considered in proportion to HUD grant funding (for example, the average CDBG grant to entitlement communities in FY 2012 was approximately $1.7 million).[28]

HUD does not anticipate the proposed regulatory changes will add much, if anything, to these costs. As noted above, the required assessments will be based on data that are already readily available on the Internet. Therefore, jurisdictions will not have to incur the expense and administrative burdens associated with collecting data. Moreover, the proposed rule does not mandate that actions be taken to address broadband needs or climate change needs. Consolidated plan jurisdictions are in the best position to decide how to expend their HUD funds. However, HUD believes that the additional analyses required by this proposed rule may highlight areas where expenditure of funds would assist in opening up economic opportunities through increased broadband access or mitigate the impact of possible natural hazard risks and climate change impacts. HUD leaves it to jurisdictions to consider any appropriate methods to promote broadband access or protect against the adverse impacts of climate change, taking into account the other needs of their communities, and available funding, as identified through the consolidated planning process.

Accordingly, HUD believes that the benefits of enhancing the ability of State and local government to comprehensively plan for housing and community development needs outweigh the minimal costs that may be associated with the revised Consolidated Plan requirements. The docket file is available for public inspection in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, please schedule an appointment to review the docket file by calling the Regulation Division at 202–402–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339.

Paperwork Reduction Act

The information collection requirements contained in this rule have been submitted to the Office of

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[20] 60 FR 1878 (January 5, 1994).

[21] See footnote 15.

[22] The *Digital Divide and Economic Benefits of Broadband Access*, Council of Economic Advisers (CEA) Issue Brief (March 2016) available online at: *https://www.whitehouse.gov/sites/default/files/page/files/20160308_broadband_cea_issue_brief.pdf.*

[23] Thom File and Camille Ryan, *Computer and Internet Use in the United States: 2013* (U.S. Census Bureau, November 2014) available online at: *http://www.census.gov/content/dam/Census/library/publications/2014/acs/acs-28.pdf.*

[24] *https://www.whitehouse.gov/energy/climate-change.*

[25] *http://nca2014.globalchange.gov/highlights/overview/climate-trends.*

[26] *http://nca2014.globalchange.gov/.*

[27] See *http://www.nist.gov/el/helping-to-build-a-nation-of-resilient-communities.cfm.*

[28] Eugene Boyd, *Community Development Block Grants: Recent Funding History* (Congressional Research Service, February 6, 2014), available online at: *https://www.hsdl.org/?view&did=750383.*

Management and Budget (OMB) for review and approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a currently valid OMB control number.

The burden of the information collections in this rule is estimated as follows:

REPORTING AND RECORDKEEPING BURDEN

Information collection	Number of respondents	Response frequency (average)*	Burden hours per response	Total burden hours
Citizen participation plan for localities (§ 91.105) and States (§ 91.115).	1,205 localities and 50 States	1	2	2,510
Housing market analysis for local governments (§ 91.210) and States (§ 91.310).	1,205 localities and 50 States	1	2	2,510
Totals	1,255	1	4	5,020

* A complete Consolidated Plan is submitted once every 3–5 years. This response number reflects one response per Consolidated Plan submission.

In accordance with 5 CFR 1320.8(d)(1), HUD is soliciting from members of the public and affected agencies comments on the following concerning this collection of information:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses.

Interested persons are invited to submit comments regarding the information collection requirements in this rule. Under the provisions of 5 CFR part 1320, OMB is required to make a decision concerning this collection of information between 30 and 60 days after the publication date. Therefore, a comment on the information collection requirements is best assured of having its full effect if OMB receives the comment within 30 days of the publication. This time frame does not affect the deadline for comments to the agency on the proposed rule, however. Comments must refer to the proposal by name and docket number (5891–P–01) and must be sent to:

HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503, Fax number: 202–395–6947, and

Ms. Colette Pollard, Reports Liaison Officer, Department of Housing and Urban Development, 451 7th Street SW., Room 2204, Washington, DC 20410

Interested persons may submit comments regarding the information collection requirements electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *http://www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Impact on Small Entities

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

As noted above in this preamble, the proposed regulatory amendment will impose minimal, if any, economic burdens on HUD grantees, irrespective of their size. The proposed rule will amend the Consolidated Plan regulations to require that States and local governments consider (1) broadband Internet service access for low- and moderate-income households to; and (2) the risk of potential natural hazards, including those that may be exacerbated due to climate change, to low- and moderate-income residents in their jurisdictions. The regulatory changes build upon their existing consolidated planning process rather than mandating completely new procedures. As discussed above, the economic costs of preparing the Consolidated Plan are not significant, and it is unlikely that the proposed changes will increase those costs since the required assessments will be mostly based on data that has already been compiled and readily available on the Internet. Jurisdictions will, therefore, not have to incur the expense and administrative burdens associated with collecting and analyzing data.

Moreover, the proposed rule does not mandate that any actions be taken in response to the required assessments. Where access to broadband Internet service is not currently available or is minimally available, States and local governments must consider ways to bring broadband Internet access to low- and moderate-income residents, including how HUD funds could be used to narrow the digital divide for these residents. Further, where low- and moderate-income communities are at risk of natural hazards, including those that may be exacerbated due to climate change, States and local governments must consider ways to incorporate hazard mitigation and resilience into their community planning and development goals, including the use of HUD funds. However, jurisdictions retain the discretion to consider the most appropriate methods to address their assessments, taking into account other needs identified as part of the consolidated planning process as well as financial and other resource constraints. This proposed rule therefore, which only requires consideration of the broadband and natural hazards resilience needs of low-income communities, has a minimal cost impact on all grantees subject to the Consolidated Planning process, whether large or small, and will not have a significant economic impact on substantial number of small entities.

Notwithstanding HUD's determination that this proposed rule will not have a significant economic effect on a substantial number of small entities, HUD specifically invites comments regarding any less burdensome alternatives to this rule that will meet HUD's objectives, as described in this preamble.

Environmental Review

This proposed rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern, or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this proposed rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule imposes either substantial direct compliance costs on state and local governments and is not required by statute, or the rule preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This proposed rule would not have federalism implications and would not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and on the private sector. This proposed rule would not impose any federal mandates on any state, local, or tribal governments, or on the private sector, within the meaning of the UMRA.

List of Subjects in 24 CFR Part 91

Aged, Grant programs—housing and community development, Homeless, Individuals with disabilities, Low- and moderate-income housing, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, HUD proposes to amend part 91 as follows:

PART 91—CONSOLIDATED SUBMISSIONS FOR COMMUNITY PLANNING AND DEVELOPMENT PROGRAMS

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 42 U.S.C. 3535(d), 3601–3619, 5301–5315, 11331–11388, 12701–12711, 12741–12756, and 12901–12912.

■ 2. In § 91.100, add a sentence to the end of paragraph (a)(1) to read as follows:

§ 91.100 Consultation; local governments.

(a) * * *

(1) * * * When preparing the consolidated plan, the jurisdiction shall also consult with public and private organizations, including broadband Internet service providers, organizations engaged in narrowing the digital divide, agencies whose primary responsibilities include the management of floodprone areas, public land or water resources, and emergency management agencies.

* * * * *

■ 3. In § 91.105, add a sentence at the end of paragraph (a)(2)(ii) to read as follows:

§ 91.105 Citizen participation plan; local governments.

(a) * * *

(2) * * *

(ii) * * * The jurisdiction shall encourage the participation of public and private organizations, including broadband Internet service providers, organizations engaged in narrowing the digital divide, agencies whose primary responsibilities include the management of floodprone areas, public land or water resources, and emergency management agencies in the process of developing the consolidated plan.

* * * * *

■ 4. In § 91.110, add a sentence at the end of paragraph (a) to read as follows:

§ 91.110 Consultation; States.

(a) * * * When preparing the consolidated plan, the State shall also consult with public and private organizations, including broadband Internet service providers, organizations engaged in narrowing the digital divide, agencies whose primary responsibilities include the management of floodprone areas, public land or water resources, and emergency management agencies.

* * * * *

■ 5. In § 91.115, add a sentence at the end of paragraph (a)(2)(ii) to read as follows:

§ 91.115 Citizen participation plan; States.

(a) * * *

(2) * * *

(ii) * * * The State shall also encourage the participation of public and private organizations, including broadband Internet service providers, organizations engaged in narrowing the digital divide, agencies whose primary responsibilities include the management of floodprone areas, public land or water resources, and emergency management agencies in the process of developing the consolidated plan.

* * * * *

■ 6. In § 91.200, redesignate paragraph (b)(3)(iv) as paragraph (b)(3)(vi), and add new paragraph (b)(3)(iv) and paragraph (b)(3)(v) to read as follows:

§ 91.200 General.

* * * * *

(b) * * *

(3) * * *

(iv) Public and private organizations, including broadband Internet service providers and organizations engaged in narrowing the digital divide;

(v) Agencies whose primary responsibilities include the management of floodprone areas, public land or water resources, and emergency management agencies; and

* * * * *

■ 7. Revise § 91.210(a) to read as follows:

§ 91.210 Housing market analysis.

(a) *General characteristics.* (1) Based on information available to the jurisdiction, the plan must describe the significant characteristics of the jurisdiction's housing market, including the supply, demand, and condition and cost of housing and the housing stock available to serve persons with disabilities, and to serve other low-income persons with special needs, including persons with HIV/AIDS and their families.

(2) Data on the housing market should include, to the extent information is available, an estimate of the number of vacant or abandoned buildings and whether units in these buildings are suitable for rehabilitation.

(3) The jurisdiction must also identify and describe any areas within the jurisdiction with concentrations of racial/ethnic minorities and/or low-income families, stating how it defines the terms "area of low-income concentration" and "area of minority concentration" for this purpose. The locations and degree of these

concentrations must be identified, either in a narrative or on one or more maps.

(4) The jurisdiction must also describe the broadband needs of housing occupied by low- and moderate-income households based on an analysis of data for its low- and moderate-income neighborhoods in the National Broadband Map. Jurisdictions may also use broadband availability data in the FCC Form 477 or other data identified by the jurisdiction, for which the source is cited in the jurisdiction's Consolidated Plan. These needs include the need for broadband wiring and for connection to the broadband service in the household units, the need for increased competition by having more than one broadband Internet service provider serve the jurisdiction.

(5) The jurisdiction must also describe the vulnerability of housing occupied by low- and moderate-income households to increased natural hazard risks associated with climate change based on an analysis of data, findings, and methods in:

(i) The National Climate Assessment, the Climate Resilience Toolkit, the Impact of Climate Change and Population Growth on the National Flood Insurance Program, or the NIST Community Resilience Planning Guide for Buildings and Infrastructure Systems;

(ii) Other climate risk-related data published by the Federal government or other State or local government climate risk-related data, including hazard mitigation plans approved by the Federal Emergency Management Agency that incorporate climate change; or

(iii) Other climate risk data identified by the jurisdiction, for which the source is cited in the jurisdiction's Consolidated Plan.

* * * * *

■ 8. In § 91.300, remove the word "and" following the semicolon at the end of paragraph (b)(3)(iii), redesignate paragraph (b)(3)(iv) as paragraph (b)(3)(vi), and add new paragraph (b)(3)(iv) and paragraph (b)(3)(v) to read as follows:

§ 91.300 General.

* * * * *

(b) * * *

(3) * * *

(iv) Public and private organizations, including broadband Internet service providers and organizations engaged in narrowing the digital divide;

(v) Agencies whose primary responsibilities include the management of floodprone areas, public land or water resources, and emergency management agencies; and

* * * * *

■ 9. Revise § 91.310(a) to read as follows:

§ 91.310 Housing market analysis.

(a) *General characteristics.* (1) Based on data available to the State, the plan must describe the significant characteristics of the State's housing markets (including such aspects as the supply, demand, and condition and cost of housing).

(2) The State must describe the broadband needs of housing in the State based on an analysis of data in the National Broadband Map. States may also use broadband availability data in the FCC Form 477 or other data identified by the jurisdiction, for which the source is cited in the jurisdiction's Consolidated Plan. These needs include the need for broadband wiring and for connection to the broadband service in the household units, the need for increased competition by having more than one broadband Internet service provider serve the jurisdiction.

(3) The State must also describe the vulnerability of housing occupied by low- and moderate-income households to increased natural hazard risks due to climate change based on an analysis of data, findings, and methods in:

(i) The National Climate Assessment, the Climate Resilience Toolkit, the Impact of Climate Change and Population Growth on the National Flood Insurance Program, or the NIST Community Resilience Planning Guide for Buildings and Infrastructure Systems;

(ii) Other climate risk-related data published by the Federal government or other State or local government climate risk-related data, including hazard mitigation plans approved by the Federal Emergency Management Agency that incorporate climate change; or

(iii) Other climate risk data identified by the jurisdiction, for which the source is cited in the jurisdiction's Consolidated Plan.

* * * * *

Dated: April 15, 2016.

Harriet Tregoning,

Principal Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 2016–11350 Filed 5–17–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 1000, 1003, 1005, 1006, and 1007

[Docket No. FR 5861–N–02]

RIN 2577–AC96

Equal Access to Housing in HUD's Native American and Native Hawaiian Programs—Regardless of Sexual Orientation or Gender Identity; Correction

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Proposed rule; correction.

SUMMARY: On May 9, 2016, HUD published a proposed rule that would revise regulations for HUD's Native American and Native Hawaiian programs to incorporate existing rules that require HUD programs to be open to all eligible individuals and families regardless of sexual orientation, gender identity, or marital status. After publication, HUD discovered an inadvertent mistake in the preamble to the document. The preamble contained incomplete information in the **FOR FURTHER INFORMATION CONTACT** section. This document revises the **FOR FURTHER INFORMATION CONTACT** section of the preamble.

DATES: This document corrects the proposed rule published on May 9, 2016 (81 FR 28037). The comment due date for that proposed rule remains unchanged as July 8, 2016.

FOR FURTHER INFORMATION CONTACT: With respect to this supplementary document, contact Camille E. Acevedo, Associate General Counsel for Legislation and Regulations, Department of Housing and Urban Development, 451 7th Street SW., Room 10238, Washington, DC 20410; telephone number 202–708–1793 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

Correction

In proposed rule FR Doc. 2016–10753, beginning on page 28037 in the issue of May 9, 2016, make the following correction in the **FOR FURTHER INFORMATION CONTACT** section. On page 28037 in the 3rd column, revise the information in the **FOR FURTHER INFORMATION CONTACT** section to read as follows:

"Randy Akers, Acting Deputy Assistant Secretary, Office of Native

American Housing Programs, Office of Public and Indian Housing, 451 7th Street SW., Room 4126, Washington, DC 20410–8000; telephone number 202–401–7914 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339."

Dated: May 12, 2016.

Camille E. Acevedo,

Associate General Counsel for Legislation and Regulations.

[FR Doc. 2016–11747 Filed 5–17–16; 8:45 am]

BILLING CODE 4210–67–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2016–0051; FRL–9946–51–Region 10]

Extension of the Attainment Date for the Oakridge, Oregon 24-Hour $PM_{2.5}$ Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to grant a 1-year extension of the attainment date for the Oakridge, Oregon nonattainment area to meet the 2006 24-hour $PM_{2.5}$ NAAQS from December 31, 2015 to December 31, 2016, on the basis that the State has met the criteria for such an extension under the Clean Air Act (CAA or Act).

DATES: Written comments must be received on or before June 17, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2016–0051 at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information that is restricted by statute from disclosure. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *http://www.regulations.gov* or at EPA Region 10, Office of Air, Waste and Toxics, 1200 Sixth Avenue, Seattle, Washington 98101. The EPA requests that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Justin Spenillo at (206) 553–6125, or email address *spenillo.justin@epa,gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever "we," "us," or "our" is used, it is intended to refer to the EPA.

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I. Background for the Proposed Action

On October 17, 2006, the EPA issued its final action to revise the $PM_{2.5}$ NAAQS to establish revised 24-hour standards (71 FR 61144). In that action, we promulgated identical revised primary and secondary $PM_{2.5}$ standards designed to protect public health and welfare that specified a 24-hour $PM_{2.5}$ average concentration of 35 $\mu g/m^3$. Specifically, the 2006 standards require that the 3-year average of the annual 98th percentile concentration may not exceed 35 $\mu g/m^3$.

On November 13, 2009, the EPA issued a final rule designating all areas throughout the country for the 2006 24-hour $PM_{2.5}$ NAAQS, effective December 14, 2009 (74 FR 58688). In that action, the EPA designated Oakridge, Oregon and a small surrounding area as a nonattainment area (Oakridge NAA) based on monitor values at the Willamette Activity Center in Oakridge. As a result of this nonattainment area designation, Oregon is required to prepare and submit to the EPA a State Implementation Plan (SIP) revision to meet attainment plan requirements and to bring the Oakridge NAA into attainment for the 2006 24-hour $PM_{2.5}$ NAAQS. The State submitted an attainment plan submission for the Oakridge NAA to the EPA by letter dated December 12, 2012 (2012 Oakridge Plan).

On January 4, 2013, the D.C. Circuit Court issued a decision in *NRDC* v. *EPA*, 706 F.3d 428, holding that the EPA erred in implementing the 1997 $PM_{2.5}$ NAAQS only pursuant to the provisions of subpart 1 of the Act, rather than the particulate matter specific provisions of subpart 4 of Part D of Title I (subpart 4). The Court did not vacate the 2007 $PM_{2.5}$ Implementation Rule for the 1997 $PM_{2.5}$ NAAQS, but remanded it to the EPA with instructions to promulgate a new implementation rule for the $PM_{2.5}$ NAAQS in accordance with the requirements of both subpart 1 and subpart 4. On June 6, 2013, consistent with the Court's remand decision, the EPA withdrew its March 2012 Implementation Guidance recommending that states rely on the 2007 $PM_{2.5}$ Implementation Rule for development of attainment plans for the 2006 24-hour $PM_{2.5}$ NAAQS. Thus, the EPA withdrew the guidance it initially provided to states for meeting attainment plan requirements for purposes of areas designated nonattainment for the 2006 24-hour $PM_{2.5}$ NAAQS, such as the Oakridge NAA.

On June 2, 2014, in response to the *NRDC* decision that it implement the $PM_{2.5}$ NAAQS pursuant to subpart 4, the EPA promulgated the "$PM_{2.5}$ Subpart 4 Nonattainment Classification and Deadline Rule" (79 FR 31566). In that action, the EPA classified all areas currently designated nonattainment for both the 1997 and 2006 $PM_{2.5}$ NAAQS as "Moderate" nonattainment areas. That rule also provided guidance to states on how to meet the subpart 4 requirements and set a deadline of December 31, 2014 for states to submit any revisions to previously submitted attainment plan submissions, as necessary to meet subpart 4 requirements. Thus, the EPA classified the Oakridge NAA as a Moderate nonattainment area for the 2006 24-hour $PM_{2.5}$ NAAQS and provided an opportunity for the state to revise the 2012 Oakridge Plan.

A Moderate $PM_{2.5}$ nonattainment area's ambient air quality status is determined in accordance with Appendix N of 40 CFR part 50. To show attainment of the current 24-hour and annual standards for $PM_{2.5}$, data from the most recent three consecutive years prior to the area's attainment date must show that $PM_{2.5}$ concentrations over the prior three year period are at or below the levels of the standards. A complete year of air quality data, as described in part 50, Appendix N, is comprised of all four calendar quarters with each quarter containing data from at least 75 percent of the scheduled sampling days.

The EPA begins processing and analyzing data related to the attainment of the $PM_{2.5}$ NAAQS after the applicable attainment date for the affected areas. Current EPA regulations, under 40 CFR part 58, set the deadline for the state to certify its air quality data in the Air Quality System (AQS) database by May 1 of the following year. Under section 179(c), the EPA is required to determine as expeditiously as practicable, but not later than 6 months after the applicable attainment date, whether a nonattainment area has attained the relevant NAAQS. In the case of a state with an area that qualifies for an extension of the attainment date under section 188(d), however, the EPA has discretion instead to extend the attainment date for an area if the state requests the extension and meets the statutory criteria for such an extension.

II. Criteria for an Extension of the Attainment Date

CAA section 188(d) allows states to apply for, and the EPA the discretion to grant, a 1-year extension to the statutory attainment date for Moderate PM_{10} (particulate matter with an aerodynamic diameter of a nominal 10 micrometers) nonattainment areas. Section 188(d) establishes two criteria that the EPA must consider to grant a requested attainment date extension: (1) The state has complied with all requirements and commitments pertaining to the area in the applicable implementation plan, and (2) no more than one exceedance of the 24-hour NAAQS level for PM_{10} has occurred in the area in the year preceding the extension year and the annual mean concentration of PM_{10} in the area for such year is less than or equal to the level of the annual standard. Section 188(d) also provides for the possibility that the EPA may grant a second 1-year extension if the Moderate area meets the specified criteria. No more than two 1-year attainment date extensions may be granted for a single nonattainment area.

The provisions of section 188(d) thus allow a state an opportunity to demonstrate that a Moderate area should continue to be classified as Moderate and not reclassified to Serious, even if the area has monitor data exceeding the level of the applicable $PM_{2.5}$ NAAQS in the calendar year preceding the otherwise applicable attainment date. Although section 188(d) provides the criteria for such an extension, the EPA believes that there are some ambiguities in the statutory language that warrant interpretation. Thus, in this action the EPA is proposing to interpret the requirements of section 188(d) in evaluating the extension request from the State.

The most significant issue that the EPA must address is how to interpret the air quality requirement of section 188(d)(2) in light of the fact that the statutory language refers to PM_{10} rather than to $PM_{2.5}$, and the fact that the air quality requirement is phrased as "no more than one exceedance" of the 24-hour PM_{10} NAAQS in the year prior to the otherwise applicable attainment date. Based upon the *NRDC* decision, there can be no doubt that the EPA must interpret the references to PM_{10} in section 188(d)(2) to encompass $PM_{2.5}$. Given that fact, however, the EPA cannot read the "no more than one exceedance" requirement to apply literally to the $PM_{2.5}$ NAAQS because of the distinct differences in the form of the PM_{10} NAAQS and the $PM_{2.5}$ NAAQS.

The statutory language addressing PM_{10} in CAA section 188 explicitly sets ambient air quality conditions for an attainment date extension in terms that relate factually to the 24-hour PM_{10} NAAQS that was in effect at the time of the 1990 Amendments of the CAA, which has a statistical form that is substantially different from the 24-hour $PM_{2.5}$ NAAQS. The requirement in 188(d)(2) states that an extension may be granted if "no more than one exceedance of the 24-hour national ambient air quality standard level for PM_{10} has occurred in the area in the year preceding the Extension Year, and the annual mean concentration of PM_{10} in the area for such year is less than or equal to the standard level." Given the form of the 24-hour PM_{10} NAAQS, the requirement that an area have no more than one "exceedance" meant that there could be no more than one monitored value over the numerical level of the NAAQS. Such an approach is logical when the form of the 24-hour NAAQS allows one exceedance per year, on average, over a three year period. By having no more than one exceedance, the state was meeting the NAAQS in that last year, even if it did not yet meet the requirements for attainment over the requisite three year period. In other words, the state would be close to attaining the NAAQS, thus making one year extension a potentially appropriate way provide additional time for a state to come into attainment without the need for a reclassification to Serious and additional SIP planning efforts. By contrast, the form of the 2006 24-hour $PM_{2.5}$ NAAQS is a 98th percentile-based form and not a "one expected exceedance" form as is the PM_{10} NAAQS. Under the form of the 2006 24-hour $PM_{2.5}$ NAAQS, there can be a number of exceedances of the numerical level of the NAAQS that are permitted and are not considered a violation of the NAAQS. Thus, under the form of the 2006 24-hour $PM_{2.5}$ NAAQS an area could be close to attaining the NAAQS in the year prior to the attainment date, even if there were one or more dates with monitored "exceedances." Therefore the statutory language requires some interpretation with regard to how it applies to the $PM_{2.5}$ NAAQS.

For this action, the EPA is proposing to interpret section 188(d) for purposes of the 2006 $PM_{2.5}$ NAAQS in a way that is equivalent to the "no more than one exceedance" condition that Congress imposed for purposes of the PM_{10} NAAQS. Accordingly, the EPA interprets the requirement to demonstrate that the area had "no more than one exceedance" of the level of the 24-hour $PM_{2.5}$ NAAQS to mean that the state must demonstrate that the area had "clean data" in the year proceeding the extension year. Thus, a state seeking an attainment date extension for a Moderate nonattainment area for a 24-hour $PM_{2.5}$ NAAQS would be required to demonstrate that the area had monitor data showing no monitored violations of the NAAQS in light of the statistical form of that particular standard (*i.e.*, for the 2006 24-hour $PM_{2.5}$ NAAQS, the 98th percentile value did not exceed 35 $\mu g/m^3$) in the calendar year prior to the applicable attainment date for the area.

An additional issue that the EPA must address concerning the air quality requirement of section 188(d)(2) is whether a state seeking an extension for purposes of a 24-hour $PM_{2.5}$ NAAQS only, must nevertheless meet the portion of section 188(d)(2) that refers to the annual ambient air quality of such an area. The EPA notes that statutory language of section 188(d) does provide that a state seeking an extension of a Moderate area attainment date must have not more than one exceedance of the 24-hour NAAQS "and" meet an annual ambient level requirement as well. The EPA believes that reading this provision to require a state to meet both tests, even when the state has an area that is designated nonattainment only for the 24-hour $PM_{2.5}$ NAAQS and is seeking an extension of only the attainment date for such NAAQS, is not a logical interpretation of the provision. Such a reading would be logical were the area at issue designated nonattainment for both the 24-hour NAAQS and the annual NAAQS, but not if designated nonattainment only for one of those standards.

The EPA is proposing to interpret section 188(d) for the 2006 24-hour $PM_{2.5}$ NAAQS to require a state only to establish that it meets the air quality requirement with respect to the 24-hour NAAQS when seeking an extension of the attainment date only for the 24-hour $PM_{2.5}$ NAAQS. The EPA believes this interpretation of section 188(d)(2) is appropriate for two main reasons. First, while most PM_{10} nonattainment areas were designated nonattainment for either just the 24-hour PM_{10} NAAQS or for both the 24-hour and annual PM_{10} NAAQS, the majority of current $PM_{2.5}$ nonattainment areas are, in contrast, designated for either the 24-hour or the annual $PM_{2.5}$ NAAQS, and should arguably only need to demonstrate clean data for the NAAQS for which the area is designated nonattainment. For those few $PM_{2.5}$ nonattainment areas designated for both 24-hour and annual $PM_{2.5}$ NAAQS, the EPA believes it also is appropriate that a state must only demonstrate clean data for the specific NAAQS for which the state is seeking an attainment date extension because such an approach is consistent with the statute's overall approach to designating nonattainment areas and implementing control strategies for each separate $PM_{2.5}$ NAAQS. Second, if an area is designated as nonattainment for both the 24-hour and annual $PM_{2.5}$ standards and receives an extension for one standard while still working toward a later attainment date for the other standard, the EPA maintains that public health protection would not be delayed because the state would still be subject to the ongoing mandate to adopt and implement measures to ensure expeditious attainment of the other standard.

Section 188(d)(1) of the Act also provides that the state must have ". . . complied with all requirements and commitments pertaining to the area in the applicable implementation plan." As with section 188(d)(2), the EPA believes that there are some ambiguities in the statutory language that warrant interpretation in order to evaluate the State's extension request. The EPA proposes to interpret this provision to mean that the state has submitted a SIP submission to address the attainment plan requirements for the applicable $PM_{2.5}$ NAAQS and that the state has implemented the control measures in the SIP submission. This proposed interpretation is based on the plain language of section 188(d) that does not explicitly require that the state comply with all requirements applicable to the area in the CAA, but merely requires that the state comply with all requirements in the applicable SIP. In other words, the EPA believes that section 188(d)(1) should be interpreted to mean that so long as the state has submitted the necessary attainment plan for the area for the applicable $PM_{2.5}$ NAAQS and is implementing the control measures in the submission, the fact that the EPA has not yet acted on such submission to make it an approved part of the applicable SIP should not be a barrier to the state obtaining an extension of the attainment date under section 188(d)(1).

Under this proposed interpretation, therefore, the state has to demonstrate that it has submitted an attainment plan to the EPA for the relevant $PM_{2.5}$ NAAQS and that the state is implementing control measures in that SIP submission. Because the extension at issue under section 188(d) is an extension of a Moderate area attainment date, it follows that the control measures in the attainment plan submission would be those measures that the State intended to meet the RACM and RACT requirements. The EPA interprets the requirement of section 188(d)(1) that the state have complied with the "requirements and commitments" of the applicable implementation plan to mean that the state must be implementing the control measures in the submitted attainment plan. The state must have adopted and submitted the attainment plan SIP revision to the EPA, but the state can qualify for the extension even if the EPA has not yet taken action on the SIP submission.

In sum, in order for the EPA to make a decision on whether to grant a 1-year attainment date extension, the state is required to submit sufficient information to demonstrate that it has both complied with all requirements and commitments in the applicable implementation plan, and that it had "clean" air quality data in the attainment year, as explained above. Any decision made by the EPA to extend the attainment date for an area would be based on facts specific to the nonattainment area at issue.

Section 188(d) does not specify the process by which the EPA should evaluate and act upon requests from states for an extension of the Moderate $PM_{2.5}$ area attainment date. However, the EPA believes that an attainment date extension should only be granted after the EPA provides notice in the **Federal Register** and an opportunity for the public to comment. Requiring notice-and-comment rulemaking allows for appropriate evaluation of the relevant criteria and facts in order to assure that the extension is granted or denied after full evaluation. This process also is consistent with past practice by the EPA in granting attainment date extensions for $PM_{2.5}$ areas. If this proposal is finalized, then the nonattainment area would remain classified as Moderate for the 2006 $PM_{2.5}$ NAAQS throughout the 2016 calendar year. After the December 31, 2016 attainment date, the EPA will evaluate air quality data and other relevant information to determine whether the area has attained the 2006 $PM_{2.5}$ NAAQS by the December 31, 2016 attainment date.

III. Meeting the Criteria for the 1-Year Extension

On December 14, 2015, the State of Oregon submitted a request to extend the Moderate area attainment date for the Oakridge NAA for the 2006 24-hour $PM_{2.5}$ NAAQS from December 31, 2015 to December 31, 2016. This request contained documentation intended to demonstrate that the State meets the criteria for a 1-year attainment date extension for this area pursuant to CAA section 188(d). On February 11, 2016, the Lane Regional Air Protection Agency (LRAPA) submitted an Oakridge Extension Request Follow-up, that provides the final quality-assured air quality data for 2015 and documentation of efforts to implement the 2012 Oakridge plan during the 2015–16 winter. The EPA is evaluating this request in light of its statutory interpretations of section 188(d) with respect to the 2006 24-hour $PM_{2.5}$ NAAQS.

A. Oakridge Air Quality Data for 2015

The LRAPA implements the CAA on behalf of the State in the Oakridge NAA. The LRAPA monitors ambient $PM_{2.5}$ at one monitoring site in the Oakridge NAA at the Willamette Activity Center, the area of expected highest concentrations. The air monitor began operation in 1989 and has monitored continuously to the present. The monitor is a Federal Reference Method sampler, sampling every third day. The

EPA has previously approved the State's monitoring network including the $PM_{2.5}$ network for Oakridge. The EPA verified in 2010 and 2013 that the $PM_{2.5}$ sample collection and filter handling procedures met Federal requirements for quality assurance and control. The LRAPA reviews and certifies all data from this monitor for compliance with these procedures and submits the data to the ODEQ. The ODEQ then submits the certified data to the EPA AQS data system.

The ODEQ submitted complete certified $PM_{2.5}$ monitor data for calendar year 2015 into the EPA AQS data system before February 28, 2016. Likewise, the state has submitted certified data for calendar years 2013 and 2014 to the EPA AQS data system. Thus, the EPA AQS data system contains sufficient data for the EPA to evaluate whether the Oakridge NAA attained the 2006 24-hour $PM_{2.5}$ NAAQS by the statutory attainment date of December 31, 2015, but also the requisite data to determine whether the Oakridge NAA was meeting the NAAQS in calendar year 2015 in order to qualify for a one year extension under section 188(d).

As explained above, the EPA is interpreting the air quality criterion of section 188(d)(2) in order to reflect the different form of the NAAQS for the PM_{10} NAAQS in effect at the time of the 1990 Amendments to the CAA versus the form of the 2006 $PM_{2.5}$ NAAQS. Under this proposed interpretation, a state could qualify for a one year extension of the Moderate area attainment date if the monitor data reflects that the area has ambient air quality that is at or below the level of the relevant $PM_{2.5}$ NAAQS for the calendar year preceding the otherwise applicable attainment date, *i.e.*, for the calendar year prior to the requested extension year. The three year average of the annual 98th percentile 24-hour $PM_{2.5}$ values for 2013–2015 in the Oakridge NAA is 37 $\mu g/m^3$ and thus the EPA cannot find that the area has attained the 24-hour standards for this 3-year period. However, the 98th percentile value for the single year of 2015 in this area is 28.9 $\mu g/m^3$, which is below the level of the 24-hour $PM_{2.5}$ NAAQS of 35 $\mu g/m^3$.

Because the Oakridge NAA is designated nonattainment only for the 2006 24-hour $PM_{2.5}$ NAAQS, the State only seeks a one year extension of the attainment date with respect to this NAAQS. As explained above, the EPA is interpreting the air quality criterion of section 188(d) to apply only with respect to the specific NAAQS for which a state seeks an extension. Thus, for a state seeking an extension of an attainment date for an area designated nonattainment only for the 24-hour NAAQS, section 188(d) does not require the EPA to evaluate the ambient air quality in the area with respect to the annual $PM_{2.5}$ NAAQS as well. Under this proposed approach, the monitored annual ambient level of $PM_{2.5}$ in the Oakridge NAA is not germane to the EPA's evaluation the extension request. However, the EPA notes that the annual design value for the Oakridge monitor is 9.2 $\mu g/m^3$ for the 2012–2014 period and the preliminary design value is 9.6 $\mu g/m^3$ for the 2013–2015 period. Thus, even if the annual ambient monitored $PM_{2.5}$ level were relevant to this extension request, the monitored $PM_{2.5}$ level in the Oakridge NAA is well below the 15 $\mu g/m^3$ level of the 2006 annual $PM_{2.5}$ NAAQS, as well as the 12 $\mu g/m^3$ level of the 2012 $PM_{2.5}$ NAAQS.

For these reasons, the EPA is proposing to find that the State meets the ambient air quality criterion for a 1-year attainment date extension for the Oakridge NAA pursuant to CAA section 188(d)(2).

B. Oakridge Requirements and Commitments in the Applicable SIP

On December 12, 2012, the Oregon Department of Environmental Quality (ODEQ) submitted a SIP revision to address attainment plan requirements for the 2006 $PM_{2.5}$ NAAQS for the Oakridge NAA (2012 Oakridge Plan). The State intended this SIP submission to meet the statutory requirements for an attainment plan for purposes of the $PM_{2.5}$ NAAQS based upon the statutory requirements and the EPA guidance for those requirements available at that time. Although the EPA anticipates that the state may elect to make an additional SIP submission to revise and update the 2012 Oakridge Plan, to date the State has not done so.

The State developed the 2012 Oakridge Plan in order to address the ambient $PM_{2.5}$ problem in this area through a control strategy designed to focus on the dominant sources of emissions in the area. The State has concluded that the violations of the 2006 24-hour $PM_{2.5}$ NAAQS in the Oakridge NAA are primarily due to emissions of direct $PM_{2.5}$ from residential wood combustion (RWC) from winter time home heating. Oakridge is a small rural community located in a valley of the western slope of the Cascade mountain range. Therefore, the State has ascertained that reducing emissions of $PM_{2.5}$ to prevent violations of the $PM_{2.5}$ NAAQS rests primarily on RWC curtailment.

The 2012 Oakridge Plan included new control measures to address RWC emissions by requiring the curtailment of RWC during times when elevated levels of $PM_{2.5}$ are predicted or occur. The RWC curtailment control measure was adopted, and is enforceable as a City of Oakridge ordinance. This ordinance, in addition to Oregon's state-wide Heat Smart program, also requires the replacement of old uncertified wood stoves with EPA certified stoves when houses containing uncertified wood stoves are sold, and requires the installation of EPA certified wood stoves in new construction. The State provided documentation in the attainment date extension request to demonstrate the implementation of the Oakridge RWC curtailment ordinance.

Subsequent to the submission of the 2012 Oakridge Plan submission, the City of Oakridge enacted revisions on November 15, 2012 and again on October 15, 2015 to strengthen the RWC ordinance which included lowering the threshold for triggering a curtailment or "burn ban," imposing a more stringent opacity limit, and requiring that only dry, seasoned wood be burned for RWC. The State plans to submit a SIP revision to the EPA in December 2016 that will include the most recent RWC ordinance revisions. The State and LRAPA provided evidence of the adoption and implementation of the new revised ordinance in support of the extension request. Although the State has not yet submitted the ordinance revisions to the EPA for evaluation, and thus the revisions are not yet part of the applicable implementation plan, the Agency nevertheless considers these revisions an important part of the State's strategy for attainment of the 2006 $PM_{2.5}$ NAAQS in the Oakridge NAA.

As explained above, the EPA is proposing to interpret the compliance with applicable implementation plan criterion of section 188(d)(1) to require that a state have made a submission intended to meet the attainment plan requirements for the 2006 $PM_{2.5}$ NAAQS and that the state be implementing the control measures in that attainment plan submission. Under this proposed interpretation, a state could qualify for a 1-year extension of the Moderate area attainment date if the state has submitted an attainment plan for the relevant $PM_{2.5}$ NAAQS and demonstrates that it is actively implementing the commitments and requirements of the attainment plan at the time of attainment date extension request.

The State developed and submitted the 2012 Oakridge Plan to the EPA for evaluation. The State also submitted information to establish that the control measures in the 2012 Oakridge Plan are in effect and are being implemented by the LRAPA at this time as part of the attainment date extension request. The EPA has reviewed the control measures of the submitted 2012 Oakridge Plan and the documentation of implementation submitted as part of the extension request. The docket provides documentation of this including the official extension request that describes supplemental strategies currently underway, an expanded city ordinance that enhances controls designed to reduce emissions from residential home heating, and local strategies and efforts to reduce emissions. Based upon this information, the EPA believes that the State and the LRAPA are complying with the requirements and commitments of the applicable implementation plan, as contemplated by section 188(d)(1).

For these reasons, the EPA is proposing to find that the State meets the compliance with the applicable implementation plan criterion for a 1-year attainment date extension for the Oakridge NAA pursuant to CAA section 188(d)(1).

IV. Summary of Proposed Action

The EPA is proposing to find that the State has met the criteria for receiving a 1-year extension to the Moderate area attainment date for the 2006 $PM_{2.5}$ NAAQS for the Oakridge NAA as provided in section 188(d) of the Act. The State is implementing the requirements and commitments in the applicable attainment plan for the $PM_{2.5}$ NAAQS in the area, and the 98th percentile 24-hour $PM_{2.5}$ air quality value for 2015 is below 35 $\mu g/m^3$. Accordingly, the State has established that it meets the criteria of section 188(d) as the EPA is proposing to interpret those requirements for purposes of the 2006 $PM_{2.5}$ NAAQS. The EPA is therefore proposing to exercise the discretion granted to the Administrator by section 188(d) of the CAA to extend the Moderate area attainment date for the Oakridge NAA from December 31, 2015 to December 31, 2016.

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: May 9, 2016.

Dennis J. McLerran,

Regional Administrator, Region 10.

[FR Doc. 2016–11628 Filed 5–17–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2016–0164; FRL–9946–358–Region 9]

Determination of Attainment of the 1-Hour Ozone National Ambient Air Quality Standard in the San Joaquin Valley Nonattainment Area in California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to determine that the San Joaquin Valley nonattainment area has attained the 1-hour ozone National Ambient Air Quality Standard. This proposed determination is based on the most recent three-year period (2012–2014) of sufficient, quality-assured, and certified data. Preliminary data for 2015 are consistent with continued attainment of the standard in the San Joaquin Valley.

DATES: Any comments must arrive by June 17, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2016–0164 at *http://www.regulations.gov,* or via email to *lee.anita@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the EPA's full public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Anita Lee, (415) 972–3958, or by email at *lee.anita@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever "we," "us," or "our" is used, we mean the EPA.

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I. Background

The Clean Air Act (CAA or "Act") requires the EPA to establish National Ambient Air Quality Standards (NAAQS or "standards") for certain widespread pollutants, such as ozone, that cause or contribute to air pollution that is reasonably anticipated to endanger public health or welfare.[1] In 1979, we promulgated an ozone NAAQS of 0.12 parts per million (ppm), one-hour average ("1-hour ozone standard").[2]

An area is considered to have attained the 1-hour ozone standard if there are no violations of the standard, as determined in accordance with the regulation codified at 40 CFR 50.9, based on three consecutive calendar years of complete, quality-assured and certified monitoring data. A violation occurs when the ambient ozone air quality monitoring data show greater than one (1.0) "expected number" of exceedances per year at any site in the area, when averaged over three consecutive calendar years. An "expected number" of exceedances is a statistical term that refers to an arithmetic average. An "expected number" of exceedances may be equivalent to the number of observed exceedances plus an increment that accounts for incomplete sampling.[3] An exceedance occurs when the maximum hourly ozone concentration during any day exceeds 0.124 ppm.[4]

The Act, as amended in 1990, required the EPA to designate as nonattainment any ozone areas that were still designated nonattainment under the 1977 Act Amendments, and any other areas violating the 1-hour ozone standard, generally based on air quality monitoring data from the 1987 through 1989 period.[5] The 1990 CAA Amendments further classified these areas, based on the severity of their nonattainment problem, as Marginal, Moderate, Serious, Severe, or Extreme.

The control requirements and date by which attainment of the one-hour ozone standard was to be achieved varied with an area's classification. Marginal areas were subject to the fewest mandated control requirements and had the earliest attainment date, November 15, 1993, while Severe and Extreme areas were subject to more stringent planning requirements and were provided more time to attain the standard.

The San Joaquin Valley (SJV or "Valley") covers approximately 23,000 square miles and includes all of Fresno, Kings, Madera, Merced, San Joaquin, Stanislaus, and Tulare counties, as well as the western half of Kern County.[6] The Valley is home to approximately four million residents. On November 6, 1991, the EPA classified the San Joaquin Valley as "Serious" nonattainment for the 1-hour ozone standard with an applicable attainment date of November 15, 1999.[7] The Valley was later reclassified by operation of law as "Severe" based on our determination that the Valley had failed to attain the standard by the 1999 deadline.[8] Later, the EPA approved a request by the State of California to reclassify the Valley as "Extreme" for the 1-hour ozone standard, with an applicable attainment date of November 15, 2010.[9]

In 1997, the EPA promulgated an 8-hour ozone standard of 0.08 ppm ("1997 8-hour ozone standard"), to replace the 1-hour ozone standard.[10] Although the 1-hour ozone standard was revoked in 2005, we continue to determine whether areas attain, or fail to attain, the 1-hour ozone standard. This is because, under the EPA's regulations governing the transition from implementation of the revoked ozone standard to implementation of the replacement ozone standard, "anti-backsliding" provisions require the continued applicability of certain 1-hour ozone control requirements in areas, such as the San Joaquin Valley, that are designated as nonattainment for the 1997 8-hour ozone standard and the connection between some of those requirements and attainment of the 1-hour ozone standard.[11] In 2008, we tightened the 8-hour ozone standard ("2008 8-hour ozone standard"),[12] and in 2015, we revoked the 1997 8-hour ozone standard, but the principles of anti-backsliding continue to apply to both revoked ozone standards.[13]

In this action, we are proposing to determine that the San Joaquin Valley has attained the 1-hour ozone standard. Under 40 CFR 50.1118, if this action is finalized as proposed and to the extent not already fulfilled, the requirement for this area to submit an attainment demonstration and associated planning requirements related to attainment of the 1-hour ozone standard, including reasonably available control measures, reasonable further progress plans, contingency measures for failure to attain, or make reasonable progress, shall be suspended until such time as the area is redesignated as attainment for the current ozone NAAQS or a redesignation substitute for the 1-hour ozone standard is approved, at which time the requirements no longer apply.[14] If, however, prior to such redesignation or approval of such redesignation substitute, the EPA determines that the area has violated the 1-hour ozone NAAQS, then the area is again required to submit such attainment-related plans.

Over the decades since the 1990 CAA Amendments, despite high rates of growth in population and regional vehicle miles traveled (VMT), 1-hour ozone concentrations in San Joaquin Valley have decreased, primarily due to emissions reductions from mobile source and consumer product control measures adopted by the California Air Resources Board (CARB) and from stationary source control measures adopted by the San Joaquin Valley Air Pollution Control District (SJVAPCD or "District"). For instance, despite regional growth, 1-hour ozone exceedance-days within the Valley (*i.e.,* number of days in a year during which the 0.12 ppm standard was violated at a (*i.e.,* at least one) monitoring site) decreased from 45 in 1990 to 7 in 2010.[15] Nonetheless, upon review of the ambient data for the three years preceding the November 15, 2010 attainment date (*i.e.,* 2008–2010), we determined that the San Joaquin Valley failed to attain the 1-hour ozone standard by that date.[16]

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[1] See sections 108 and 109 of the Act.

[2] See 44 FR 8202, February 8, 1979.

[3] See 40 CFR part 50, appendix H. Because, in this context, the term "exceedances" refers to days (during which the daily maximum hourly ozone concentration exceeded 0.124 ppm), the maximum possible number of exceedances in a given year is 365 (or 366 in a leap year).

[4] For more information, please see "National 1-hour primary and secondary ambient air quality standards for ozone" (40 CFR 50.9) and "Interpretation of the 1-Hour Primary and Secondary National Ambient Air Quality Standards for Ozone" (40 CFR part 50, appendix H).

[5] See section 107(d)(4) of the Act. See also 56 FR 56694, November 6, 1991.

[6] See 40 CFR 81.305.

[7] See 56 FR 56694, November 6, 1991.

[8] See 66 FR 56476, November 8, 2001.

[9] See 69 FR 20550, April 16, 2004.

[10] See 62 FR 38856, July 18, 1997.

[11] See, generally, 40 CFR 51.905.

[12] 73 FR 16436 (March 27, 2008).

[13] 80 FR 12264 (March 6, 2015). See, generally, 40 CFR 51.1105.

[14] See 40 CFR 50.1118 and 80 FR 12264, March 6, 2015.

Since then, the trend towards fewer 1-hour ozone exceedance-days has continued, and on February 11, 2016, CARB requested that the EPA determine that the San Joaquin Valley has attained the 1-hour ozone standard (also referred to as a "clean data determination").[17] As part of its request for a clean data determination for the 1-hour ozone standard for the San Joaquin Valley, CARB submitted its own staff report and appendices, a letter dated July 13, 2015 from the District to the EPA and CARB requesting a clean data determination, the District's staff report to support its clean data determination request, and an ozone study final report prepared for the District.[18]

In addition to the request for a clean data determination, the District provided documentation in its staff report intended to support a finding that attainment of the 1-hour ozone standard is due to permanent and enforceable emission reductions. In our final implementation rule for the 2008 ozone standard (80 FR 12264, March 6, 2015), we established a mechanism, referred to as a "redesignation substitute," through which an area may shift to contingency status those requirements, such as penalty fee program requirements under CAA section 185, to which an area had remained subject under the EPA's anti-backsliding regulations governing the transition from revoked ozone standards (such as the 1-hour ozone standard) to current ozone standards. To invoke this mechanism, a state must submit a demonstration that the area has attained the revoked ozone NAAQS due to permanent and enforceable emission reductions and that the area will maintain the revoked NAAQS for 10 years from the date of the EPA's approval of this showing.[19] In this action, we are not taking action on the District's demonstration that attainment of the 1-hour ozone standard in the San Joaquin Valley is due to permanent and enforceable emission reductions because it is not relevant for the purposes of a clean data determination, but we will consider the District's demonstration in a separate rulemaking if and when it is supplemented with the 10-year maintenance demonstration element also needed to invoke the redesignation substitute mechanism in 40 CFR 51.1105(b).

II. The EPA's Analysis

A determination of whether an area's air quality meets the 1-hour ozone NAAQS is generally based upon three years of complete, quality-assured and certified air quality monitoring data gathered at established State and Local Air Monitoring Stations (SLAMS) in the nonattainment area and entered into the EPA's Air Quality System (AQS) database.[20] A determination of whether an area meets the 1-hour ozone standard relies upon a review of the daily maximum ozone levels. Under 40 CFR part 50, appendix H, a daily maximum ozone level is defined to be the highest hourly ozone value recorded for the day. This daily maximum value is considered valid if 75 percent of the hours from 9:01 a.m. to 9:00 p.m. were measured or if the highest hour is greater than the level of the standard. A missing daily maximum ozone value may be assumed to be less than the level of the standard if the valid daily maxima on both the preceding day and the following day do not exceed 75 percent of the NAAQS. Data from air monitors operated by state or local agencies in compliance with the EPA monitoring requirements must be submitted to the AQS database. Monitoring agencies annually certify that these data are accurate to the best of their knowledge. Accordingly, the EPA relies primarily on data in its AQS database when determining the attainment status of an area.[21]

A. Analysis of Ambient Air Quality Data

When the EPA determined that the San Joaquin Valley had failed to attain the November 15, 2010 attainment date, the Agency made its determination based on 2008 to 2010 data from a network of 22 ozone monitoring sites.[22] By 2015, the number of ozone monitoring sites in San Joaquin Valley had increased to 27, 24 of which are designated as regulatory and from which data may be compared to the NAAQS.[23] All of these sites monitor ozone concentrations on a continuous basis using ultraviolet absorption monitors.

CARB or SJVAPCD operates 23 of the monitoring sites: Seven within Kern County, six within Fresno County, two within Madera, San Joaquin, Stanislaus, and Tulare counties, and one within Kings and Merced counties.[24] CARB annually certifies that the data the agency submits to AQS are quality-assured, including data collected by CARB at monitoring sites in San Joaquin Valley.[25] SJVAPCD does the same for monitors operated by the District.[26] In addition, the National Park Service (NPS) operates two ozone monitoring sites in Sequoia National Park in Tulare County; the Tachi-Yokut Tribe operates a monitoring site at the Santa Rosa Rancheria in Kings County; and the Chukchansi Indians of California operate a monitoring site at the Picayune Rancheria in Madera County.

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[15] See table A–1 in appendix A to the San Joaquin Valley 2013 Plan for the Revoked 1-Hour Ozone Standard, adopted by the District on September 19, 2013.

[16] See 76 FR 82133, December 30, 2011.

[17] See Letter from Richard W. Corey, Executive Officer, CARB, to Jared Blumenfeld, Regional Administrator, EPA Region IX, dated February 11, 2016.

[18] See "San Joaquin Valley 1-Hour Ozone Clean Data Determination" dated February 8, 2016, prepared by CARB; "San Joaquin Valley 1-Hour Ozone Clean Data Determination—Appendices" dated February 8, 2016 prepared by CARB; letter from Seyed Sadredin, Executive Officer/Air Pollution Control Officer, San Joaquin Valley Unified Air Pollution Control District, to Jared Blumenfeld, EPA Region IX, and Richard Corey, CARB, dated July 13, 2015; "Attainment Determination Request for the Revoked 1-Hour Ozone Standard" dated July 13, 2015 prepared by the San Joaquin Valley Air Pollution Control District; and "Sonoma Technology, Inc., "Ozone Concentrations In and Around the City of Arvin," final report prepared for the District, May 2014 ("Arvin Ozone Saturation Study").

[19] 40 CFR 51.1105(b).

[20] Generally, a "complete" data set for determining attainment of the ozone standard is one that includes three years of data with an average percent of days with valid monitoring data greater than 90 percent with no single year less than 75 percent. See 40 CFR part 50, appendix I.

[21] See 40 CFR 50.9; 40 CFR part 50, appendix H; 40 CFR part 53; 40 CFR part 58, appendices A, C, D and E. All data are reviewed to determine the area's air quality status in accordance with 40 CFR part 50, appendix H.

[22] 76 FR 56694, at 56698 (September 14, 2011).

[23] Relevant changes in the ozone monitoring network include the relocation of the Fresno–North First Street site (AQS ID: 06–019–0008) approximately 0.25 miles north to the Fresno–Garland site (AQS ID: 06–019–0011), the relocation of the Arvin-Bear Mountain site (AQS ID: 06–029–5001) approximately 2 miles north to the Arvin-Di Giorgio site (AQS ID: 06–029–5002), and the establishment of new ozone monitors at Tranquility (AQS ID: 06–019–2009) in Fresno County, at Bakersfield Municipal Airport (AQS ID: 06–029–2012) in Kern County, in the City of Madera (AQS ID: 06–039–2010) in Madera County, and in Porterville (AQS ID: 06–107–2010) in Tulare County.

[24] See figure 1 in SJVAPCD's *2015 Air Monitoring Network Plan* (August 28, 2015) for a map of the ambient air monitors in the San Joaquin Valley.

[25] See, *e.g.,* letter from Ravi Ramalingam, Chief, Consumer Products and Air Quality Assessment Branch, Air Quality Planning and Science Division, CARB, to Deborah Jordan, Director, Air Division, U.S. EPA Region IX, certifying calendar year 2014 ambient air quality data and quality assurance data, dated May 8, 2015.

[26] See, *e.g.,* letter from Sheraz Gill, Director of Strategies and Incentives, letter to Deborah Jordan, Director, Air Division, U.S. EPA Region IX, certifying calendar year 2014 ambient air quality data and quality assurance data, dated July 8, 2015.

The Sequoia National Park—Ash Mountain (AQS ID 06–107–0009) NPS monitoring site is designated as regulatory and comparable to the NAAQS. NPS annually certifies that the data it submits to AQS are quality-assured.[27] One NPS site within Tulare County, Sequoia National Park—Lower Kaweah (AQS ID 06–107–0006), is designated as non-regulatory and not comparable to the NAAQS. The EPA notes that the two monitoring sites located in Indian country, Santa Rosa Rancheria (AQS ID 06–031–0500) and Picayune Rancheria (AQS ID 06–019–0500), are designated as non-regulatory and not comparable to the NAAQS.

Table 1 summarizes the expected 1-hour ozone exceedances, per year and as an average over the 2012–2014 period, at the regulatory monitoring sites in the San Joaquin Valley. Generally, the highest ozone concentrations in the San Joaquin Valley have occurred in the central and southern portions of the nonattainment area, but in recent years, the highest ozone concentrations have occurred in the central portion of the valley (*i.e.*, within Fresno County). As shown in Table 1, the highest three-year average of expected exceedances at any site in the San Joaquin Valley for 2012–2014 is 0.7 at Fresno—Sierra Skypark in Fresno County. The calculated exceedance rate of 0.7 represents attainment of the 1-hour ozone NAAQS (a three-year average of expected exceedances less than or equal to 1). Thus, taking into account the extent and reliability of the applicable ozone monitoring network, and the data collected and summarized in Table 1, we propose to determine that the San Joaquin Valley has attained the 1-hour ozone NAAQS (as defined in 40 CFR part 50, appendix H). Preliminary 2015 data have not been certified but are consistent with the continued attainment of the 1-hour ozone NAAQS in the San Joaquin Valley.

TABLE 1—ONE-HOUR OZONE DATA FOR THE SAN JOAQUIN VALLEY ONE-HOUR OZONE NONATTAINMENT AREA [1]

Site (AQS ID)	Expected exceedances by year			Expected exceedances 3-yr average
	2012	2013	2014	2012–2014
FRESNO COUNTY:				
Clovis—Villa (06–019–5001)	0.0	0.0	0.0	0.0
Fresno—Drummond Street (06–019–0007)	1.0	0.0	0.0	0.3
Fresno—Garland (06–019–0011)	1.0	0.0	0.0	0.3
Fresno—Sierra Skypark (06–019–0242)	1.0	0.0	1.1	0.7
Parlier (06–019–4001)	1.0	0.0	0.0	0.3
Tranquility (06–019–2009)	0.0	0.0	0.0	0.0
KERN COUNTY:				
Arvin—Di Giorgio (06–029–5002)	0.0	0.0	0.0	0.0
Bakersfield—Muni (06–029–2012)	0.0	0.0	0.0	[2]0.0
Bakersfield—California (06–029–0014)	0.0	0.0	0.0	0.0
Edison (06–029–0007)	0.0	0.0	0.0	0.0
Maricopa (06–029–0008)	0.0	0.0	0.0	0.0
Oildale (06–029–0232)	0.0	0.0	0.0	0.0
Shafter (06–029–6001)	0.0	0.0	0.0	0.0
KINGS COUNTY:				
Hanford—Irwin (06–031–1004)	0.0	0.0	0.0	0.0
MADERA COUNTY:				
Madera—Pump Yard (06–039–0004)	0.0	0.0	0.0	0.0
Madera—City (06–039–2010)	0.0	0.0	0.0	0.0
MERCED COUNTY:				
Merced—Coffee (06–047–0003)	0.0	0.0	0.0	0.0
SAN JOAQUIN COUNTY:				
Stockton—Hazelton (06–077–1002)	0.0	0.0	0.0	0.0
Tracy—Airport (06–077–3005)	0.0	0.0	0.0	0.0
STANISLAUS COUNTY:				
Modesto—14th Street (06–099–0005)	0.0	0.0	0.0	0.0
Turlock (06–099–0006)	0.0	0.0	0.0	0.0
TULARE COUNTY:				
Porterville (06–107–2010)	0.0	0.0	0.0	0.0
Sequoia National Park—Ash Mountain (06–107–0009)	0.0	0.0	0.0	0.0
Visalia—Church Street (06–107–2002)	0.0	0.0	0.0	0.0

[1] Source: Quicklook Report, “*20160311_QLRpt_SJV_1hrO3_2012-2015.pdf,*” March 11, 2016; and “*20160411_QLRpt_SJV_1hrO3_2012-2015.xlsx,*” April 11, 2016 (in the docket for this proposed action).

[2] Based on CARB's missing data analysis for this site, at most one exceedance could have been recorded during the first half of 2012 if the site had been operational during that period. Assuming such an exceedance had occurred, the 3-year average of expected exceedances for the 2012–2014 period at the Bakersfield-Municipal Airport site would have been 0.3, which is less than the corresponding value at Fresno-Sierra Skypark (0.7) and less than the NAAQS.

As noted above, a “complete” data set for determining attainment of the ozone standard is generally one that includes three years of data with an average percent of days with valid monitoring data greater than 90 percent with no single year less than 75 percent. Based on these criteria, the data summarized in Table 1 from all of the sites meet the criteria over the 2012 to 2014 period except for the Bakersfield—Municipal Airport site (AQS ID: 06–029–2012). The Bakersfield—Municipal Airport site began operation on July 1, 2012 and although completeness was greater than 90 percent for the period of the year it was operating, total completeness for the entire year, including the period prior to establishment of the monitor, was 48 percent. Completeness was greater than 90 percent at the Bakersfield—Municipal Airport site in 2013 and 2014.

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[27] See, *e.g.*, letter from Barkley Sive, Program Manager, NPS, to Lew Weinstock, U.S. EPA, certifying 2014 ozone data, incorrectly dated April 29, 2014, received by EPA via electronic mail on April 30, 2015.

To address the data gap at the Bakersfield—Municipal Airport, CARB prepared a missing data analysis to identify an upper bound on the ozone concentrations and exceedance days that might have been recorded at this site during the first half of 2012 if it had been operational during that time.[28] To identify an upper bound, CARB calculated the maximum differences between daily maximum 1-hour ozone measurements occurring on the same days from the three surrounding sites (Oildale, Bakersfield—California Avenue, and Edison) and the Bakersfield—Municipal Airport site during the first six months of 2013 and 2014 and applied the maximum differences to the highest daily maximum hourly concentrations measured at the three nearby ozone sites during the first half of 2012. The results showed that at most one exceedance could have been measured at the Bakersfield—Municipal Airport during the first six months of 2012 if it had been operational during that time. Based on our review, we find CARB's methods for estimating an upper bound on ozone concentrations and exceedances at the Bakersfield—Municipal Airport site to be acceptable and agree with CARB's conclusions drawn from the analysis. Thus, we find that incompleteness of the 2012 data set from the Bakersfield—Municipal Airport site does not preclude an attainment determination for the San Joaquin Valley that relies, in part, on 2012 data.

B. Analysis of 1-Hour Ozone Trends in the San Joaquin Valley

In support of its request to EPA for a Clean Data Determination, CARB submitted analyses of the 1-hour ozone design value and concentration trends, along with analyses of topography, meteorology, and ozone precursor emissions in the Valley. Based on its analyses, CARB concluded that the ozone site within the Valley with the maximum 1-hour ozone concentration is currently located in the Fresno Metropolitan Statistical Area (MSA). Between 1990 and 2007, the maximum 1-hour ozone concentrations in the Valley alternated between the Bakersfield MSA in the southern portion of the Valley and the Fresno MSA in the central portion of the Valley.[29] In 2008 the location of the maximum 1-hour ozone concentration site shifted from the Bakersfield MSA (at the Edison monitoring site for 2006–2007) to the Fresno MSA (at the Clovis—N. Villa Avenue monitoring site in 2008–2010), where it has remained through 2015 (at the Fresno—Sierra Skypark monitoring site in 2012–2014).[30] CARB provided detailed evidence that the maximum 1-hour ozone concentrations in the Bakersfield MSA have decreased and the location of the maximum 1-hour ozone concentration has occurred in the Fresno MSA over last seven years (2008–2014).

CARB's analyses suggest that the Valley's topography, weather, and transport patterns strongly influence the geographic distribution of ozone, resulting in lower levels in the north, with higher levels in the central and southern portions of the Valley. In addition, CARB's analysis of emission inventories show decreasing trends in anthropogenic emissions of nitrogen oxides and reactive organic gases throughout the Valley from 2000 to 2014, with the fastest rates of decrease expected in the Bakersfield MSA, providing further support that the Valley's design value is likely to continue to occur in the Fresno MSA.

The Arvin—Bear Mountain monitoring site in the Bakersfield MSA was closed in 2010. Prior to its ceasing operation, a monitor intended to replace it began operating nearby at the Arvin—Di Giorgio site. The request to replace the Arvin—Bear Mountain monitoring site with the Arvin—Di Giorgio monitoring site and the EPA's analysis of the request are discussed in section II.C., below. At the time of its closure, the Arvin—Bear Mountain monitoring site had not recorded the maximum ozone concentration in the Valley in more than five years. However, in order to ensure that all sites that had been violating the 1-hour ozone NAAQS would be attaining the standard, CARB conducted a detailed analysis of the daily maximum 1-hour ozone concentrations expected at the Arvin—Bear Mountain monitoring site following its closure in 2010 because it had been one of the Valley sites that, in some prior years, recorded the highest ozone concentration in the Valley. CARB conducted rank-by-rank regression analyses and comparisons using 2010 data from the Arvin—Bear Mountain, Arvin—Di Giorgio, and Edison monitoring sites to estimate daily maximum 1-hour ozone concentrations and estimated expected exceedances at the Arvin—Bear Mountain monitoring site for 2011–2015 had the monitor remained operational until this time. CARB's analyses indicated that the Arvin—Bear Mountain monitoring site would have attained the 1-hour ozone NAAQS in the 2012–2014 period and would have continued to attain the standard for 2013–2015 based on the most recent preliminary data for 2015.[31] CARB's analyses also concluded that the three-year average of estimated expected exceedances of 0.3 at the Arvin—Bear Mountain monitoring site for both the 2012–2014 and 2013–2015 periods would have been less than the corresponding values at the Fresno—Sierra Skypark monitoring site (0.7 for 2012–2014 and 0.4 for 2013–2015).

In addition to CARB's analyses, the District conducted predictive regression calculations of daily maximum 1-hour ozone concentrations for 2012 through 2014 at the Arvin—Bear Mountain and Arvin—Di Giorgio monitoring sites.[32] Although the District used different methods, their results are consistent with the results from CARB's analyses, indicating that ozone concentrations at the Arvin—Bear Mountain monitoring site would have attained the 1-hour ozone NAAQS during 2012–2014. The District's analyses also indicate the location of the maximum 1-hour concentration ozone site within the Fresno MSA and provide support for the shift, in 2008, of the Valley's maximum site from the Bakersfield region to the Fresno region. This is further supported by monitoring data at the Arvin—Bear Mountain monitoring site that show that in the last five years of Arvin—Bear Mountain's monitor operation prior to its 2010 closure, the Valley's maximum 1-hour ozone concentration did not occur at the Arvin—Bear Mountain monitoring site.

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[28] See CARB's missing data analysis in appendix A to "San Joaquin Valley 1-Hour Ozone Clean Data Determination" dated February 8, 2016.

[29] See pp. 21–22, CARB "San Joaquin Valley 1-Hour Ozone Clean Data Determination" dated February 8, 2016.

[30] See Table 9, p.22, CARB "San Joaquin Valley 1-Hour Ozone Clean Data Determination" dated February 8, 2016.

[31] See pp. 18–19 and Appendix B, CARB "San Joaquin Valley 1-Hour Ozone Clean Data Determination" dated February 8, 2016.

[32] See "Attainment Determination Request for the Revoked 1-Hour Ozone Standard" dated July 13, 2015 prepared by the San Joaquin Valley Air Pollution Control District.

Based on our review of the submitted documentation, we find that CARB's and the District's methods and analyses regarding 1-hour ozone trends in the San Joaquin Valley and estimates of post-2010 ozone concentrations and expected exceedances at the Arvin—Bear Mountain site to be reasonable and agree with the conclusions drawn therefrom.

C. Analysis of Monitoring Network Adequacy

Within the San Joaquin Valley, CARB and the District are jointly responsible for assuring that the area meets air quality monitoring requirements. The SLAMS network of ozone monitors in the Valley includes monitors operated by the District and monitors operated by CARB. The District submits annual monitoring network plans to the EPA. The District's network plans describe the various monitoring sites operated by the District as well as those operated by CARB. These plans discuss the status of the air monitoring network, as required under 40 CFR 58.10.[33]

The EPA reviews the District's annual network plans and conducts technical systems audits and has generally found the combined ambient air monitoring network meets or exceeds the requirements for the minimum number of SLAMS monitoring sites for ozone and is in compliance with the applicable reporting requirements in 40 CFR part 58 for ozone except for the requirement to identify a maximum concentration ozone site within the Bakersfield MSA.[34]

Specifically, 40 CFR part 58 requires, among other things, that at least one ozone site for each MSA must be designated to record the maximum concentration for that particular area. The closure of the Arvin—Bear Mountain site without subsequent approval of a replacement site prevented the designation of a maximum concentration ozone site for the Bakersfield MSA. On April 29, 2016, CARB submitted a request letter to the EPA for the relocation of the San Joaquin Valley Arvin—Bear Mountain ozone air monitoring site to the Arvin—Di Giorgio air monitoring site, which is 2.2 miles away and began operation prior to closure of the Arvin—Bear Mountain site.[35] On May 2, 2016, EPA approved the relocation request based on a thorough review of all nearby available site options.[36] Approval of the replacement site for the Arvin—Bear Mountain monitoring site resolves the ozone ambient air monitoring network issue for the Bakersfield MSA. The EPA is determining that the ozone monitoring network in the Valley is adequate based on the following: The foregoing analyses provided by CARB and the District indicating that the Valley's maximum 1-hour ozone concentration site has shifted away from the Bakersfield MSA to sites located in the Fresno MSA and that 1-hour ozone design values that would have occurred at the Arvin—Bear Mountain monitoring site post-2010 are consistent with attainment; the EPA's approval of the Arvin—Bear Mountain monitoring site relocation request; and the fact that the replacement for the Arvin—Bear Mountain monitoring site (*i.e.*, Arvin—Di Giorgio) has been in operation since prior to the closure of the Arvin—Bear Mountain monitoring site.

III. Proposed Action and Request for Public Comment

The EPA is proposing to determine that the San Joaquin Valley has attained the 1-hour ozone standard based on sufficient, quality-assured and certified ambient air quality monitoring data for the 2012–2014 monitoring period. Preliminary data for 2015 are consistent with the continued attainment of the standard in San Joaquin Valley.

If we finalize this determination as proposed, to the extent not already fulfilled, the requirements for the state to submit attainment demonstrations and associated reasonably available control measures, reasonable further progress plans, contingency measures for failure to attain or make reasonable progress and other plans related to attainment of the 1-hour ozone standard for San Joaquin Valley shall be suspended until such time as the area is redesignated as attainment for the current ozone NAAQS or a redesignation substitute for the 1-hour ozone standard is approved, at which time the requirements no longer apply.[37] If, however, prior to such redesignation or approval of such redesignation substitute, the EPA determines that San Joaquin Valley has violated the 1-hour ozone NAAQS, then the area is again required to submit such attainment-related plans.[38]

The EPA is soliciting public comments on the issues discussed in this document or on other relevant matters. We will accept comments from the public on this proposal for the next 30 days. We will consider these comments before taking final action.

IV. Statutory and Executive Order Reviews

This action proposes to make a determination based on air quality data and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and,
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed clean data determination does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), and will not impose substantial direct costs on tribal governments or preempt tribal law.

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[33] See SJVAPCD's "2015 Air Monitoring Network Plan", dated August 28, 2015.

[34] See, *e.g.*, letter from Deborah Jordan, Director, Air Division, EPA Region IX, to James Goldstene, Executive Officer, California Air Resources Board, dated October 22, 2012, transmitting the findings from the EPA's 2011 Technical Systems Audit.

[35] See letter from Karen Magliano, Chief, Air Quality Planning and Science Division, California Air Resources Board, to Meredith Kurpius, Manager, Air Quality Analysis Office, EPA Region IX, dated April 29, 2016.

[36] See letter from Meredith Kurpius, Manager, Air Quality Analysis Office, EPA Region IX, to Karen Magliano, Chief, Air Quality Planning and Science Division, California Air Resources Board, dated May 2, 2016.

[37] See 40 CFR 51.1118.

[38] *Id.*

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Oxides of nitrogen, Ozone, Volatile organic compounds.

Dated: May 3, 2016.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2016–11630 Filed 5–17–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0711; FRL–9946–60–Region 9]

Approval and Promulgation of Implementation Plans; California; San Joaquin Valley; Revisions to Motor Vehicle Emissions Budgets for Ozone and Particulate Matter

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve and conditionally approve revisions to the State of California's State Implementation Plan (SIP) for the San Joaquin Valley (SJV) area. The revisions consist of an update to the Motor Vehicle Emissions Budgets ("budgets") for nitrogen oxides (NO$_X$) and volatile organic compounds (VOCs) for the 1997 8-hour ozone national ambient air quality standard (NAAQS or "standard") for the SJV ozone nonattainment area; for NO$_X$ and fine particulate matter (PM$_{2.5}$) for the 2006 24-hour PM$_{2.5}$ standard for the SJV PM$_{2.5}$ nonattainment area; and for NO$_X$ and course particulate matter (PM$_{10}$) for the 1987 24-hour PM$_{10}$ standard for the SJV PM$_{10}$ maintenance area. The EPA is proposing to approve the SJV ozone and PM$_{2.5}$ revised budgets and conditionally approve the PM$_{10}$ budgets in accordance with the requirements of the Clean Air Act (CAA or "Act") and the EPA's regulations.

DATES: Comments must be received on or before June 17, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2015–0711 at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Docket: The index to the docket and documents in the docket for this action are generally available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.*, copyrighted material, large maps), and some may not be publicly available in either location (*e.g.*, CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Karina O'Connor, Air Planning Office (AIR–2), U.S. Environmental Protection Agency, Region IX, (775) 434–8176, *oconnor.karina@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, whenever "we," "us," or "our" is used, we mean the EPA. This **SUPPLEMENTARY INFORMATION** section is arranged as follows:

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I. What action is the EPA proposing?

The EPA is proposing action on a SIP revision submitted by the State of California ("State") on November 13, 2015. The SIP submittal revises budgets applicable to control strategy or maintenance plans for the SJV for three different NAAQS. We are proposing to approve revised budgets for the 1997 8-hour ozone standard and the 2006 24-hour PM$_{2.5}$ standard. We are also proposing to conditionally approve revised budgets for the 1987 24-hour PM$_{10}$ standard. Should the EPA later finalize the revised budgets as proposed herein, they will replace the SJV's existing budgets for the 1997 8-hour ozone standard, the 2006 24-hour PM$_{2.5}$ standard, and the 1987 24-hour PM$_{10}$ standard. At that time, the previously-approved or adequate budgets would no longer be applicable for transportation conformity purposes, and the revised budgets would need to be used as of the effective date of the final approval.

II. Background

A. Standards Applicable to Today's Action

In 1997, the EPA revised the ozone standard to set the acceptable level of ozone in the ambient air at 0.08 parts per million, averaged over an 8-hour period. 62 FR 38856 (July 18, 1997).[1] On April 15, 2004, the EPA designated the SJV as nonattainment for the 1997 8-hour ozone standard and classified the area as "Serious" under CAA section 181(a)(1) and 40 CFR 51.903(a), Table 1. See 69 FR 23858 at 23888–89 (April 30, 2004) and 40 CFR 81.305. In 2007, California requested that the EPA reclassify the SJV from "Serious" to "Extreme" nonattainment for the 1997 8-hour ozone standard under CAA section 181(b)(3). We granted California's request on May 5, 2010 and reclassified the SJV to Extreme for the

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[1] In 2008, the EPA revised and further strengthened the 8-hour ozone standard by setting the acceptable level of ozone in the ambient air at 0.075 ppm, averaged over an 8-hour period ("2008 8-hour ozone standard"). 73 FR 16436 (March 27, 2008). In 2015, the EPA further tightened the 8-hour ozone standard to 0.070 ppm. 80 FR 65292 (October 26, 2015).

1997 8-hour ozone standard effective June 4, 2010. See 75 FR 24409.

In 2006, the EPA revised the $PM_{2.5}$ 24-hour standard to provide increased protection of public health by lowering its level from 65 micrograms per cubic meter ($\mu g/m^3$) to 35 $\mu g/m^3$ (40 CFR 50.13). On November 13, 2009, the EPA designated the SJV as nonattainment for the 2006 24-hour $PM_{2.5}$ standard. 74 FR 58688 (November 13, 2009). This designation became effective on December 14, 2009 (40 CFR 81.305).[2]

In 1987, the EPA revised the particulate matter standard, replacing standards for total suspended particulates with new standards applying only to PM_{10}. 52 FR 24633 (July 1, 1987). In 1990, the SJV was designated nonattainment for PM_{10}. 56 FR 11101 (March 15, 1991). In 2006, the 24-hour PM_{10} standard was retained, but the annual standard was revoked effective December 18, 2006. 71 FR 61144 (October 17, 2006).[3] In 2008, the EPA approved a PM_{10} maintenance plan and redesignated the SJV to attainment for the 24-hour PM_{10} standard. 73 FR 66759 (November 12, 2008).

For all three pollutants, the SJV nonattainment area includes all of seven counties, including Fresno, Kings, Madera, Merced, San Joaquin, Stanislaus, and Tulare counties, and the western half of Kern County. See the NAAQS-specific tables in 40 CFR 81.305.

B. SIP Budgets and Transportation Conformity

Under the CAA, states are required to submit, at various times, control strategy SIP revisions and maintenance plans for nonattainment and maintenance areas for a given NAAQS. These emission control strategy SIP revisions (*e.g.,* reasonable further progress (RFP) and attainment demonstration SIP revisions) and maintenance plans include motor vehicle emissions budgets of on-road mobile source emissions for criteria pollutants and/or their precursors to address pollution from cars and trucks. SIP budgets are the portions of the total allowable emissions that are allocated to on-road vehicle use that, together with emissions from other sources in the area, will provide for RFP, attainment or maintenance. The budget serves as a ceiling on emissions from an area's planned transportation system. For more information about budgets, see the preamble to the November 24, 1993, transportation conformity rule (58 FR 62188).

Under section 176(c) of the CAA, transportation plans, Transportation Improvement Programs (TIPs), and transportation projects must "conform" to (*i.e.,* be consistent with) the SIP before they can be adopted or approved. Conformity to the SIP means that transportation activities will not cause new air quality violations, worsen existing air quality violations, or delay timely attainment of the NAAQS or delay an interim milestone. The transportation conformity regulations can be found at 40 CFR part 93.

Before budgets can be used in conformity determinations, the EPA must affirmatively find the budgets adequate. However, adequate budgets do not supersede approved budgets for the same CAA purpose. If the submitted SIP budgets are meant to replace budgets for the same purpose, the EPA must approve the budgets, and can affirm that they are adequate at the same time. Once the EPA approves the submitted budgets, they must be used by state and federal agencies in determining whether transportation activities conform to the SIP as required by section 176(c) of the CAA. The EPA's substantive criteria for determining the adequacy of budgets are set out in 40 CFR 93.118(e)(4).

C. What is the EMFAC model?

The EMFAC model (short for EMission FACtor) is a computer model developed by the California Air Resources Board (CARB). CARB updates EMFAC on a regular basis and releases new versions generally every three or four years. The current version can estimate emission rates for on-road mobile sources ("motor vehicles") operating in California for calendar years from 2000 to 2050. Pollutant emissions for VOCs,[4] carbon monoxide (CO), NO_X, PM_{10}, $PM_{2.5}$, lead, carbon dioxide (CO_2), and sulfur oxides are outputs generated by the model. Emissions are calculated for fifty-one different vehicle classes composed of passenger cars, various types of trucks and buses, motorcycles, and motor homes.

EMFAC is used to calculate current and future inventories of motor vehicle emissions at the state, air district, air basin, or county level. EMFAC contains default vehicle activity data, and the option of modifying that data, so it can be used to estimate a motor vehicle emissions inventory in tons/day for a specific year, month, or season, and as a function of ambient temperature, relative humidity, vehicle population, mileage accrual, miles of travel and speeds. Thus the model can be used to make decisions about air pollution policies and programs at the local or state level. Inventories based on EMFAC are also used to meet the federal CAA's SIP and transportation conformity requirements.

D. What versions of EMFAC are currently in use in California?

Most budgets in the California SIP were developed using EMFAC2007 (released by CARB in October 2007) or EMFAC2011 (released by CARB in September 2011). The EPA approved EMFAC2007 at 73 FR 3464 (January 18, 2008) and EMFAC2011 at 78 FR 14533 (March 16, 2013) for all areas in California.

EMFAC2011 was considered a major update to previous versions of EMFAC and most budgets in the California SIP were updated with EMFAC2011 in the 2012–2014 timeframe. EMFAC2011 included a new model structure, new data and methodologies regarding calculation of motor vehicle emissions, and revisions to implementation data for control measures.

E. What changes does EMFAC2014 reflect?

The EPA approved EMFAC2014 for use in SIP revisions and transportation conformity at 80 FR 77337 (December 14, 2015). EMFAC2014 includes significant changes to its model interface, new data and methodologies regarding calculation of motor vehicle emissions and revisions to implementation data for control measures. EMFAC2014 includes updated data on car and truck activity, and emissions reductions associated with CARB's Advanced Clean Cars regulations.[5] Motor vehicle fleet age, vehicle types and vehicle population have also been updated based on 2000–2012 California Department of Motor Vehicle data. EMFAC2014 incorporates new temperature and humidity profiles. Each of these changes impact emission factors for each area in California. In addition to changes to truck activity, EMFAC incorporates updated vehicle miles traveled (VMT) for all vehicle classes. The new model interface for EMFAC2014 allows users to update the default VMT data and speed profiles by vehicle class for different future scenarios. CARB's Web site describes these and other model changes at: *http://www.arb.ca.gov/msei/categories.htm#onroad_motor_vehicles.*

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[2] The SJV area is also designated nonattainment for the 1997 annual and 24-hour $PM_{2.5}$ standards.

[3] In 2013, the EPA again retained the 24-hour PM_{10} standard of 150 ug/m³. See 78 FR 3086 (January 15, 2013).

[4] California plans sometimes use the term Reactive Organic Gases (ROG) for VOC. These terms are essentially synonymous. For simplicity, we use the term VOC herein to mean either VOC or ROG.

[5] For further information, see the EPA's January 9, 2013 waiver of preemption for the Advanced Clean Cars regulations at 78 FR 2112.

F. Existing Adequate or Approved Budgets

The EPA previously approved the SJV budgets for the 1997 8-hour ozone standard and the 24-hour PM$_{10}$ standard. The ozone budgets were included in the EPA's approval of the SJV 2007 8-hour Ozone Plan ("2007 Ozone Plan") at 77 FR 12652 (March 1, 2012), which established NO$_X$ and VOC budgets for 2011, 2014, 2017, 2020, and 2023.[6] The PM$_{10}$ budgets were included in the EPA's approval of the 2007 PM$_{10}$ Maintenance Plan and Request for Redesignation ("2007 PM$_{10}$ Plan") at 73 FR 66759 (November 12, 2008), which established direct PM$_{10}$ and NO$_X$ budgets for 2005 and 2020.[7]

The EPA previously proposed to approve the SJV budgets for the 2006 24-hour PM$_{2.5}$ standard. The PM$_{2.5}$ budgets were included in the EPA's proposed approval of the SJV 2012 PM$_{2.5}$ Plan ("2012 PM$_{2.5}$ Plan") at 80 FR 1816 (January 13, 2015). The EPA found the 2017 PM$_{2.5}$ budgets in the SJV 2012 PM$_{2.5}$ Plan to be adequate at 81 FR 22194 (April 15, 2016), establishing direct PM$_{2.5}$ and NO$_X$ budgets for 2017. As of May 2, 2016, these budgets must be used to determine conformity of transportation plans and TIPs to the control strategy plan for the SJV for the 2006 24-hour PM$_{2.5}$ standard.[8]

The current EPA-approved budgets for the 1997 8-hour ozone standard and PM$_{10}$ standard were developed using EMFAC2007, and the adequate budgets for the 2006 24-hour PM$_{2.5}$ standard were developed using EMFAC2011. In the SJV, the eight county-level Metropolitan Planning Organizations (MPOs) and the U.S. Department of Transportation (DOT) are the relevant transportation agencies that must use approved or adequate budgets in determining the conformity of transportation plans and TIPs within the SJV region.

G. Submission of Revised Budgets Based on EMFAC2014

The revised budgets for the 1997 8-hour ozone, 2006 24-hour PM$_{2.5}$, and 24-hour PM$_{10}$ standards were adopted by the CARB on October 22, 2015.[9] They were submitted to the EPA on November 13, 2015.[10]

III. CAA Procedural and Administrative Requirements for SIP Submittals

CAA sections 110(a)(1) and (2) and 110(l) require a state to provide reasonable public notice and opportunity for public hearing prior to the adoption and submittal of a SIP or SIP revision. To meet this requirement, every SIP submittal should include evidence that adequate public notice was given and an opportunity for a public hearing was provided consistent with the EPA's implementing regulations in 40 CFR 51.102.

CARB satisfied applicable statutory and regulatory requirements for reasonable public notice and hearing prior to adoption and submittal of the revised budgets. In the documentation included as part of the November 13, 2015 SIP revision submittal, CARB provided evidence of the required public notice and opportunity for public comment prior to its October 22, 2015 public hearing and adoption of the revised budgets. We find, therefore, that the submittal of the revised budgets meets the procedural requirements for public notice and hearing in CAA sections 110(a) and 110(l).

CAA section 110(k)(1)(B) requires the EPA to determine whether a SIP submittal is complete within 60 days of receipt. This section also provides that any plan submittal that the EPA has not affirmatively determined to be complete or incomplete will be deemed complete by operation of law six months after the date of submittal. The EPA's SIP completeness criteria are found in 40 CFR part 51, Appendix V. The EPA determined that CARB's November 13, 2015 SIP revision submittal was complete on April 21, 2016.[11]

IV. What are the criteria for approval of revised budgets?

Under section 110(l) of the CAA, SIP revisions must not interfere with any applicable requirements concerning attainment or RFP or any other applicable requirement of the Act. Generally, the EPA reviews budgets for adequacy or approval in the context of the Agency's review of a control strategy implementation plan (*i.e.,* attainment or RFP plan) or maintenance plan. However, revisions to budgets can be approved without comprehensive updates to the related control strategy implementation or maintenance plan if the plan, with the new level of motor vehicle emissions contained in the revised budgets, continues to meet applicable requirements (*i.e.,* RFP, attainment, or maintenance). EPA policy guidance suggests that a state may revise the motor vehicle emissions inventories and related budgets without revising their entire SIP consistent with section 110(l) if: (1) The SIP continues to meet applicable requirements when the previous motor vehicle emissions inventories are replaced with new MOtor Vehicle Emission Simulator (MOVES) base year and milestone, attainment, or maintenance year inventories; and (2) the state can document that growth and control strategy assumptions for non-motor vehicle sources continue to be valid and any minor updates do not change the overall conclusions of the SIP.[12] The EPA's policy guidance for MOVES can be applied to EMFAC because EMFAC is a California-specific emissions model analogous to MOVES.

In addition, revised budgets that are intended to replace adequate (but not approved) budgets must meet the adequacy criteria found in our transportation conformity regulations at 40 CFR 93.118(e)(4). These criteria include endorsement by the Governor (or designee); prior consultation among relevant air and transportation agencies; clear identification and precise quantification of the budgets; consistency of the budgets, when considered with all other emissions sources, with applicable requirements for RFP, attainment or maintenance; consistency with and clear relation to the emissions inventory and control measures; and explanation and documentation of changes relative to previously submitted budgets. In this instance, the adequacy criteria do not apply to our review of the revised budgets for the 2007 Ozone Plan or the 2007 PM_{10} Plan because the budgets they would replace are approved budgets. The adequacy criteria do, however, apply to our review of the revised budgets for the 2012 $PM_{2.5}$ Plan because the budgets from that plan have been found adequate, but are not yet approved.

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[6] The approved 2007 Ozone Plan includes the SJV 2007 Ozone Plan (as revised 2008 and 2011) and SJV-related portions of CARB's 2007 State Strategy (revised 2009 and 2011).

[7] The approved SIP includes the 2007 PM$_{10}$ Maintenance Plan and Request for Redesignation, September 20, 2007, and technical corrections by CARB to the 2020 budgets for Merced, San Joaquin, Stanislaus and Tulare counties in the 2007 PM$_{10}$ Plan. See May 13, 2008 letter to Mr. Wayne Nastri from James N. Goldstene.

[8] Also see letter, Elizabeth J. Adams, Deputy Director, Air Division, EPA Region 9, to Richard W. Corey, Executive Officer, CARB, April 1, 2016 with enclosures.

[9] CARB Resolution No. 15–50, October 22, 2015.

[10] Letter, Richard W. Corey, Executive Officer, CARB to Jared Blumenfeld, Regional Administrator, EPA Region 9, November 13, 2015 with enclosures.

[11] Letter, Deborah Jordan, Director, Air Division, EPA Region 9, to Richard W. Corey, Executive Officer, CARB, dated April 21, 2016.

[12] *Policy Guidance on the Use of MOVES2014 for State Implementation Plan Development, Transportation Conformity, and Other Purposes,* EPA–420–B–14–008, July 2014. See question and answer #6 on page 7. Available online at: *http://www3.epa.gov/otaq/models/moves/documents/420b14008.pdf.* MOVES is a model that states use to estimate on-road emissions for SIP development, transportation conformity determinations, and other purposes. Also see examples of EPA rulemakings involving replacement of budgets in response to a MOVES update, *e.g.,* Allentown-Bethlehem-Easton (79 FR 28435, May 16, 2014) and Beaumont/Port Arthur (78 FR 7672, February 4, 2013).

V. Summary of Changes to Budgets and the EPA's Analysis of the State's Submittal

Table 1 lists the revised budgets by subarea included in the State's submittal for the SJV budgets applicable to the 1997 8-hour ozone, 2006 24-hour $PM_{2.5}$, and the 24-hour PM_{10} standards. CARB developed the revised budgets using EMFAC2014 and the travel activity projections provided by the San Joaquin Valley MPOs consistent with the 2015 Federal TIP. As such, we find that the revised budgets reflect the most recent planning forecasts and are based on the most recent emission factor data and approved calculation methods. A comparison of the current approved or adequate budgets with the revised budgets and a discussion of the EPA's proposed action on each set of budgets is provided further below.

TABLE 1—SAN JOAQUIN VALLEY REVISED BUDGETS DEVELOPED USING EMFAC2014 [13]

County subarea	1997 8-hour ozone standard						2006 24-hour $PM_{2.5}$ standard		PM_{10} standard	
	NO_X (tons per summer day)			VOC (tons per summer day)			Direct $PM_{2.5}$ (tons per winter day)	NO_X (tons per winter day)	Direct PM_{10} (tons per annual day)	NO_X (tons per annual day)
	2017	2020	2023	2017	2020	2023		2017		2020
Fresno	29.9	24.3	14.6	8.7	6.8	5.6	1.0	32.1	7.0	25.4
Kern (SJV)	26.8	22.4	12.9	6.9	5.7	4.8	0.8	28.8	7.4	23.3
Kings	5.5	4.7	2.7	1.4	1.1	0.9	0.2	5.9	1.8	4.8
Madera	5.5	4.5	2.7	2.0	1.6	1.3	0.2	6.0	2.5	4.7
Merced	10.3	8.5	5.1	2.7	2.1	1.7	0.3	11	3.8	8.9
San Joaquin	14.1	11.3	7.3	6.4	5.1	4.3	0.6	15.5	4.6	11.9
Stanislaus	11.3	9.2	5.8	4.1	3.2	2.7	0.4	12.3	3.7	9.6
Tulare	10.3	8.1	4.9	4.0	3.1	2.5	0.4	11.2	3.4	8.4

Note: CARB calculated the revised budgets for the SJV plans by taking the sum of the county-by-county emissions results from EMFAC and rounding the SJV-wide total up to the nearest whole ton for NO_X and to the nearest tenth of a ton for VOC, $PM_{2.5}$ and PM_{10}; then re-allocating to the individual counties based on the ratio of each county's contribution to the total; and then rounding each county's emissions to the nearest tenth of a ton using the conventional rounding method.

A. Review of Revised Budgets for the 1997 8-Hour Ozone Standard

Tables 2 and 3 below compare the current EPA-approved NO_X and VOC budgets developed using EMFAC2007 with the revised budgets developed using EMFAC2014. The budgets are provided by subarea and apply to the 1997 8-hour ozone standard.

TABLE 2—COMPARISON OF SAN JOAQUIN VALLEY OZONE BUDGETS FOR NO_X FOR THE 1997 8-HOUR OZONE STANDARD

[Tons per summer day]

County subarea	2017			2020			2023		
	Current	Revised	Net change	Current	Revised	Net change	Current	Revised	Net change
Fresno	22.6	29.9	7.3	17.7	24.3	6.6	13.5	14.6	1.1
Kern (SJV)	31.7	26.8	−4.9	25.1	22.4	−2.7	18.6	12.9	−5.7
Kings	6.7	5.5	−1.2	5.3	4.7	−0.6	4.0	2.7	−1.3
Madera	5.8	5.5	−0.3	4.7	4.5	−0.2	3.6	2.7	−0.9
Merced	12.4	10.3	−2.1	9.9	8.5	−1.4	7.4	5.1	−2.3
San Joaquin	15.6	14.1	−1.5	12.4	11.3	−1.1	10.0	7.3	−2.7
Stanislaus	10.6	11.3	0.7	8.4	9.2	0.8	6.4	5.8	−0.6
Tulare	10.1	10.3	0.2	8.1	8.1	0.0	6.2	4.9	−1.3
Totals	115.5	113.7	−1.8	91.6	93.0	1.4	69.7	56.0	−13.7

Note: CARB calculated the revised ozone budgets by taking the sum of the county-by-county emissions results from EMFAC and rounding the SJV-wide total up to the nearest whole ton for NO_X and nearest tenth of a ton for VOC; then re-allocating to the individual counties based on the ratio of each county's contribution to the total; and then rounding each county's emissions to the nearest tenth of a ton using the conventional rounding method. The previously approved budgets for ozone were rounded up to the nearest tenth of a ton at the county level.

TABLE 3—COMPARISON OF SAN JOAQUIN VALLEY OZONE BUDGETS FOR VOC FOR THE 1997 8-HOUR OZONE STANDARD

[Tons per summer day]

County subarea	2017			2020			2023		
	Current	Revised	Net change	Current	Revised	Net change	Current	Revised	Net change
Fresno	9.3	8.7	−0.6	8.3	6.8	−1.5	8.0	5.6	−2.4
Kern (SJV)	8.7	6.9	−1.8	8.2	5.7	−2.5	7.9	4.8	−3.1
Kings	1.8	1.4	−0.4	1.7	1.1	−0.6	1.6	0.9	−0.7
Madera	2.2	2.0	−0.2	2.0	1.6	−0.4	1.9	1.3	−0.6
Merced	3.2	2.7	−0.5	2.9	2.1	−0.8	2.8	1.7	−1.1
San Joaquin	7.2	6.4	−0.8	6.4	5.1	−1.3	6.3	4.3	−2.0
Stanislaus	5.6	4.1	−1.5	5.0	3.2	−1.8	4.7	2.7	−2.0

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[13] The county-specific budgets are set forth in attachment A to CARB Resolution 15–50. Attachment A constitutes the SIP revision adopted by CARB on October 22, 2015 and submitted on November 13, 2015. CARB provided information and analysis supporting the SIP revision in a staff report titled *Updated Transportation Conformity Budgets for the San Joaquin Valley Ozone, $PM_{2.5}$, and PM_{10} State Implementation Plans*, release date September 21, 2015.

TABLE 3—COMPARISON OF SAN JOAQUIN VALLEY OZONE BUDGETS FOR VOC FOR THE 1997 8-HOUR OZONE STANDARD—Continued

[Tons per summer day]

County subarea	2017			2020			2023		
	Current	Revised	Net change	Current	Revised	Net change	Current	Revised	Net change
Tulare	5.8	4.0	−1.8	5.3	3.1	−2.2	4.9	2.5	−2.4
Totals	43.8	36.2	−7.6	39.8	28.7	−11.1	38.1	23.8	−14.3

Note: CARB calculated the revised ozone budgets by taking the sum of the county-by-county emissions results from EMFAC and rounding the SJV-wide total up to the nearest whole ton for NO_X and to the nearest tenth of a ton for VOC; then re-allocating to the individual counties based on the ratio of each county's contribution to the total; and then rounding each county's emissions to the nearest tenth of a ton using the conventional rounding method. The previously approved budgets for ozone were rounded up to the nearest tenth of a ton at the county level.

The revised NO_X and VOC budgets for 2017, 2020, and 2023 are intended to replace the EPA-approved NO_X and VOC budgets in 2007 Ozone Plan developed for the 1997 8-hour ozone standard. A comparison of the current budgets with the revised budgets is shown in tables 2 and 3. The tables show that the NO_X and VOC totals for the revised budgets are less than the current budgets for all years, except 2020 for NO_X, which shows a slight increase of 1.4 tpd or 1.4% when compared to the prior budget.

First, we note that the 2007 Ozone Plan relied upon motor vehicle emissions inventories, from which the budgets[14] were derived, to demonstrate compliance with RFP and attainment requirements. With respect to the RFP requirement, we found that the 2007 Ozone Plan provided a significant surplus of NO_X emissions reductions beyond those necessary to meet the RFP requirement. See table 11 of our proposed approval of the 2007 Ozone Plan (76 FR 57862, September 16, 2011). As shown in tables 2 and 3, with one exception, the revised regional total motor vehicle emissions estimates submitted by CARB for VOC and NO_X for 2017, 2020 and 2023 are lower than the corresponding estimates from the plan as approved in 2012. As such, the replacement of the older budgets with the revised budgets would not change the conclusion that the 2007 Ozone Plan meets the requirements for RFP. The exception, the 1.4 tpd of NO_X in 2020, is too minor to affect the conclusion that the 2007 Ozone Plan will continue to meet the RFP requirement in that year given the significant surplus in NO_X emissions reductions in that year.

Second, we have reviewed the analysis CARB prepared in support of the revised budgets and contained in the staff report included with the November 13, 2015 SIP revision submittal. In that analysis, CARB prepared updated NO_X and VOC emissions inventories from all sources (*i.e.*, stationary, area, on-road and non-road sources) in the SJV for 2017, 2020, and 2023. These updated inventories provide a basis for comparison with the corresponding inventories from the 2007 Ozone Plan. We would expect that most current emissions estimates from all sources in SJV in 2017, 2020, and 2023 would be lower than those included in the 2007 Ozone Plan because they reflect control measures adopted since the plan was approved, and as shown below in tables 4 and 5, the updated regional emissions for 2017, 2020, and 2023, including the revised budgets, are approximately 20 tpd, 15 tpd, and 34 tpd lower for NO_X and 0 tpd, 4 tpd, and 12 tpd lower for VOCs, respectively, than the corresponding figures in the EPA-approved plan. The most significant differences between the inventories are from large decreases in the actual reported emissions for several point source categories (*i.e.*, cogeneration, oil and gas production, food and agriculture, glass manufacturing and composting), compared to their projected emissions in the EPA-approved plan.[15] Other significant differences include updates to: (1) Agricultural acreage burned; (2) CARB's off-road source emissions using a newer suite of category-specific models developed to support recent CARB regulations; and (3) animal population estimates and VOC emission factors for livestock operations. The current emissions estimates for 2023 (161 tpd of NO_X, and 327 tpd of VOC) are consistent with the attainment target level[16] for the 1997 ozone standard (141 tpd of NO_X, and 342 tpd of VOC) given the continued implementation of the long-term element of the control strategy of the 2007 Ozone Plan to develop new technologies or to improve existing control technologies as approved by EPA under section 182(e)(5).

Therefore, we find that the 2007 Ozone Plan will continue to meet applicable requirements for RFP and attainment when the previously-approved EMFAC2007-based budgets are replaced with the revised EMFAC2014-based budgets, and that the changes in the growth and control strategy assumptions for non-motor vehicle sources do not change the overall conclusions of the 2007 Ozone Plan. As such, we find that approval of the revised NO_X and VOC budgets for the 2007 Ozone Plan for 2017, 2020 and 2023 as shown in table 1 would not interfere with attainment or RFP or any other requirement of the Act and would thereby comply with section 110(l), and we propose to approve them on that basis.

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[14] In San Joaquin Valley plans, the motor vehicle emissions inventories are essentially the same as the budgets. Historically, CARB has set the budget for the SJV MPOs by rounding the motor vehicle emissions estimate to the nearest tenth of a ton. With more recent plans and for the revised budgets, CARB rounds the regional total motor vehicle emissions inventories up to the nearest whole ton (for NO_X) or the nearest tenth of a ton (for ROG, $PM_{2.5}$ and PM_{10}) and then re-allocates the emissions to the various counties based on the ratio of the county-specific motor vehicle emissions to the regional total. The re-allocated county-specific emissions estimate is rounded conventionally to the nearest tenth of a ton, which then constitutes the budget. See the attachment to CARB's staff report included in the November 13, 2015 submittal in support of the SIP revision (*i.e.*, the revised budgets).

[15] *Comparing the Emission Inventories for the San Joaquin Valley State Implementation Plans*, CARB, March 30, 2016. Attachment to email from Dennis Wade, CARB, to John Ungvarsky, EPA Region 9, March 30, 2016.

[16] See table 9 on page 57858 of our proposed approval of the 2007 Ozone Plan at 76 FR 57846 (September 16, 2011).

[17] The emissions shown for the approved ozone plan are from appendix A–3 and B–3 of CARB's 2011 update to the 2007 Ozone Plan titled "Proposed 8-Hour Ozone State Implementation Plan Revisions and Technical Revisions to the $PM_{2.5}$ State Implementation Plan Transportation Conformity Budgets for the South Coast and San Joaquin Valley Air Basins" (release date: June 20, 2011). CARB's updated emissions inventory is presented in CARB's staff report submitted as part of the November 13, 2015 SIP revision submittal.

TABLE 4—COMPARISON OF NO_X INVENTORIES ASSOCIATED WITH CURRENT AND REVISED BUDGETS FOR THE 1997 8-HOUR OZONE STANDARD

[Tons per summer day][17]

Inventory category	Emissions inventory in approved ozone plan			Updated emissions inventory			Net change		
	2017	2020	2023	2017	2020	2023	2017	2020	2023
Stationary and Area	55	53	53	36	36	35	−19	−17	−18
On-road	115	91	69	113	92	55	−2	1	−14
Non-road	89	80	73	89	82	70	0	2	−3
Totals	259	225	195	239	210	161	−20	−15	−34

Note: Because of rounding conventions, totals may not reflect individual subcategories. For the net change, a negative number indicates a reduction in emissions, and a positive number indicates an increase in emissions relative to the corresponding figure in the 2007 Ozone Plan.

TABLE 5—COMPARISON OF VOC INVENTORIES ASSOCIATED WITH CURRENT AND REVISED BUDGETS FOR THE 1997 8-HOUR OZONE STANDARD

[Tons per summer day][18]

Inventory category	Emissions inventory in approved ozone plan			Updated emissions inventory			Net change		
	2017	2020	2023	2017	2020	2023	2017	2020	2023
Stationary and Area	229	235	244	255	263	272	26	28	28
On-road	43	39	37	36	29	24	−7	−10	−13
Non-road	57	57	57	38	35	32	−19	−22	−25
Totals	329	331	339	329	327	327	0	−4	−12

Note: Because of rounding conventions, totals may not reflect individual subcategories. For the net change, a negative number indicates a reduction in emissions, and a positive number indicates an increase in emissions relative to the corresponding figure in the 2007 Ozone Plan.

B. Review of Revised Budgets for the 2006 24-Hour $PM_{2.5}$ Standard

Table 6 below compares the current direct $PM_{2.5}$ and NO_X budgets developed using EMFAC2011 that were recently found adequate for transportation conformity purposes with the revised budgets developed using EMFAC2014. The budgets are provided by subarea and apply to the 2006 24-hour $PM_{2.5}$ standard.

TABLE 6—COMPARISON OF SAN JOAQUIN VALLEY 2017 $PM_{2.5}$ BUDGETS FOR $PM_{2.5}$ AND NO_X FOR THE 2006 24-HOUR $PM_{2.5}$ STANDARD

[Tons per winter day]

County subarea	Direct $PM_{2.5}$			NO_X		
	Current	Revised	Net change	Current	Revised	Net change
Fresno	0.9	1.0	0.1	25.2	32.1	6.9
Kern (SJV)	1.0	0.8	−0.2	34.4	28.8	−5.6
Kings	0.2	0.2	0.0	7.2	5.9	−1.3
Madera	0.2	0.2	0.0	7.0	6.0	−1.0
Merced	0.4	0.3	−0.1	13.7	11	−2.7
San Joaquin	0.6	0.6	0.0	15.9	15.5	−0.4
Stanislaus	0.5	0.4	−0.1	12.0	12.3	0.3
Tulare	0.4	0.4	0.0	10.7	11.2	0.5
Totals	4.2	3.9	−0.3	126.1	122.8	−3.3

Note: CARB calculated the revised $PM_{2.5}$ budgets by taking the sum of the county-by-county emissions results from EMFAC and rounding the SJV-wide total up to the nearest whole ton for NO_X and to the nearest tenth of a ton for direct $PM_{2.5}$; then re-allocating to the individual counties based on the ratio of each county's contribution to the total; and then rounding each county's emissions to the nearest tenth of a ton using the conventional rounding method. The existing adequate $PM_{2.5}$ budgets were calculated in the same manner.

The revised 2017 direct $PM_{2.5}$ and NO_X budgets are intended to replace the adequate 2017 $PM_{2.5}$ and NO_X budgets in the 2012 $PM_{2.5}$ Plan developed for the 2006 24-hour $PM_{2.5}$ standard. A comparison of the prior budgets with the revised budgets, as shown in table 6, indicates that the totals for the revised direct $PM_{2.5}$ and NO_X budgets are less than the current budgets.

First, we note that the 2012 $PM_{2.5}$ Plan relied upon motor vehicle emissions inventories, from which the budgets were derived, for year 2017 to demonstrate compliance with RFP requirements for that year. In our proposed partial approval of the 2012 $PM_{2.5}$ Plan, we proposed to approve the RFP demonstration as meeting the requirements of CAA section 172(c)(2) for year 2017 based on emissions projections in the plan for that year that reflect full implementation of a control strategy that satisfies the Moderate area control requirements (*i.e.,* RACM/RACT at a minimum). See 80 FR 1816, at 1834–1837 (January 13, 2015). We deemed such a showing to be sufficient to meet the RFP requirement in an area that cannot practicably attain the PM$_{2.5}$ standard by the applicable Moderate area attainment date. The revised motor vehicle emissions estimates used to develop the revised budgets continue to reflect full implementation of a control strategy that satisfies the Moderate area control requirements, and as such, replacement of the EMFAC2011-based motor vehicle emissions budgets from the 2012 PM$_{2.5}$ Plan with the revised EMFAC2014-based motor vehicle emissions budgets would not change the proposal to approve the RFP demonstration for 2017 in the 2012 PM$_{2.5}$ Plan.

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[18] The emissions shown for the approved ozone plan are from appendix A–3 and appendix B–3 of CARB's 2011 update to the 2007 Ozone Plan titled *Proposed 8-Hour Ozone State Implementation Plan Revisions and Technical Revisions to the $PM_{2.5}$ State Implementation Plan Transportation Conformity Budgets for the South Coast and San Joaquin Valley Air Basins* (release date June 20, 2011). CARB's updated emissions inventory is presented in CARB's staff report submitted as part of the November 13, 2015 SIP revision submittal.

Second, we have reviewed the analysis that CARB prepared in support of the revised budgets and contained in the staff report included with the November 13, 2015 SIP revision submittal. In that analysis, CARB included a comparison of the estimated direct PM$_{2.5}$ and NO$_X$ emissions inventories from all sources (*i.e.,* stationary, area, on-road and non-road sources) for 2017 with those from the 2012 PM$_{2.5}$ Plan. As shown below in table 7, the total emissions for 2017 associated with the revised budgets are approximately 7 tpd lower for direct PM$_{2.5}$ and 6 tpd lower for NO$_X$ when compared to the total emissions inventory in the 2012 PM$_{2.5}$ Plan containing the current budgets. The differences include updates to: Agricultural acreage burned; locomotive and recreational boat emissions; and farming operations.

Therefore, we find that the 2012 PM$_{2.5}$ Plan continues to meet applicable requirements for RFP in 2017 when the EMFAC2011-based budgets are replaced with the new EMFAC2014-based budgets, and that the changes in the growth and control strategy assumptions for non-motor vehicle sources do not change the overall conclusions regarding the 2012 PM$_{2.5}$ Plan's demonstration of RFP for 2017. As such, we find that approval of the revised direct PM$_{2.5}$ and NO$_X$ budgets for the 2012 PM$_{2.5}$ Plan for year 2017 as shown in table 1 would not interfere with attainment or RFP or any other requirement of the Act and would thereby comply with section 110(l), and we propose to approve them on that basis.

In addition, we have reviewed the revised direct PM$_{2.5}$ and NO$_X$ budgets for compliance with the adequacy criteria and find that, in addition to being consistent with the 2017 RFP demonstration, they are clearly identified and precisely quantified and meet all of the other criteria in 40 CFR 93.118(e)(i)–(vi). See the EPA memorandum documenting review of the budgets for compliance with the criteria in 40 CFR 93.118(e) that has been placed in the docket for this rulemaking.

Lastly, approval of the revised budgets would not affect our January 13, 2015 proposal, or rationale therein, to approve the trading mechanism as described on page C–32 in appendix C of the 2012 PM$_{2.5}$ Plan as enforceable components of the transportation conformity program in the SJV for the 2006 PM$_{2.5}$ standard with the condition, as explained in our January 13, 2015 proposal, that trades are limited to substituting excess reductions in NO$_X$ for increases in PM$_{2.5}$. See 80 FR at 1816, at 1841 (January 13, 2015).

TABLE 7—COMPARISON OF 2017 PM$_{2.5}$ AND NO$_X$ INVENTORIES ASSOCIATED WITH CURRENT AND REVISED BUDGETS FOR THE 2006 24-HOUR PM$_{2.5}$ STANDARD

[Tons per winter day][19]

Inventory category	2017 emissions inventory in 2012 PM$_{2.5}$ plan		Updated 2017 emissions inventory		Net change	
	PM$_{2.5}$	NO$_X$	PM$_{2.5}$	NO$_X$	PM$_{2.5}$	NO$_X$
Stationary	8.9	27.4	8.7	28.5	−0.2	1.1
Area	46.8	15.6	41.2	11.7	−5.6	−3.9
On-road	4.2	125.6	3.7	122.3	−0.5	−3.3
Non-road	3.6	64.3	4.1	62.9	0.5	−1.4
Totals	63.6	232.9	57.7	225.4	−5.9	−7.5

Note: Because of rounding conventions, totals may not reflect individual subcategories. For the net change, a negative number indicates a reduction, and a positive number indicates an increase relative to the corresponding figure in the 2012 PM$_{2.5}$ Plan.

C. Review of Revised Budgets for the 24-Hour PM$_{10}$ Standard

Table 8 below compares the current EPA-approved direct PM$_{10}$ and NO$_X$ budgets developed using EMFAC2007 with the revised budgets developed using EMFAC2014. The budgets are provided by subarea and apply to the 24-hour PM$_{10}$ standard.

TABLE 8—COMPARISON OF SAN JOAQUIN VALLEY PM$_{10}$ 2020 BUDGETS FOR DIRECT PM$_{10}$ AND NO$_X$ FOR THE PM$_{10}$ STANDARD

[Annual average tons per day]

County subarea	Direct PM$_{10}$[20]			NO$_X$		
	Current	Revised	Change	Current	Revised	Change
Fresno	16.1	7.0	−9.1	23.2	25.4	2.2
Kern (SJV)	14.7	7.4	−7.3	39.5	23.3	−16.2
Kings	3.6	1.8	−1.8	6.8	4.8	−2.0

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[19] CARB's updated emissions inventory is presented in CARB's staff report submitted as part of the November 13, 2015 SIP revision submittal.

TABLE 8—COMPARISON OF SAN JOAQUIN VALLEY PM_{10} 2020 BUDGETS FOR DIRECT PM_{10} AND NO_X FOR THE PM_{10} STANDARD—Continued

[Annual average tons per day]

County subarea	Direct PM_{10} [20]			NO_X		
	Current	Revised	Change	Current	Revised	Change
Madera	4.7	2.5	−2.2	6.5	4.7	−1.8
Merced	6.4	3.8	−2.6	12.9	8.9	−4.0
San Joaquin	10.6	4.6	−6.2	17.0	11.9	−5.1
Stanislaus	6.7	3.7	−3.0	10.8	9.6	−1.2
Tulare	9.4	3.4	−6.0	10.9	8.4	−2.5
Totals	72.2	34.2	−38.0	127.6	97.0	−30.6

Note: CARB calculated the revised PM_{10} budgets by taking the sum of the county-by-county emissions results from EMFAC and rounding the SJV-wide total up to the nearest whole ton for NO_X and to the nearest tenth of a ton for direct PM_{10}; then re-allocating to the individual counties based on the ratio of each county's contribution to the total; and then rounding each county's emissions to the nearest tenth of a ton using the conventional rounding method. The previously approved budgets for PM_{10} were rounded up to the nearest tenth of a ton at the county level.

The revised direct PM_{10} and NO_X budgets for 2020 are intended to replace the EPA-approved PM_{10} and NO_X budgets developed using EMFAC2007 for the 2007 PM_{10} Plan.

First, we note that the 2007 PM_{10} Plan relied upon motor vehicle emission inventories, from which the budgets were derived, to demonstrate maintenance of the PM_{10} standard through 2020. Maintenance through 2020 was demonstrated in the 2007 PM_{10} Plan using a combination of chemical mass balance receptor modeling to identify emission source contributions by chemical species and rollback techniques. See pages 6–11 of the 2007 PM_{10} Plan. Given the modeling methods used to demonstrate maintenance, it is not possible to precisely calculate the change in concentration associated with the substitution of the approved budgets with the revised budgets. However, given that the revised budgets, when summed for the SJV region, are lower than the regional sum for the approved budgets, replacement of the approved budgets with the revised budgets would not undermine the maintenance demonstration in the 2007 PM_{10} Plan.

Second, we have reviewed the analysis CARB prepared in support of the revised budgets. To further demonstrate that the changes to the direct PM_{10} and NO_X budgets are consistent with the 2007 PM_{10} Plan for the 24-hour PM_{10} standard, CARB's analysis included a comparison of the estimated direct PM_{10} and NO_X emissions inventories from all sources (including stationary, area, on-road and non-road sources) for 2020. As shown below in table 9, the total emissions for 2020 associated with the revised budgets are approximately 10.2 tpd lower for direct PM_{10} and 121.0 tpd lower for NO_X when compared to the total emissions inventory in the 2007 PM_{10} Plan. The lower estimates for NO_X are primarily due to greater reductions in NO_X from stationary sources than had been assumed in the 2007 PM_{10} Plan.[21]

The primary differences between the inventories in the 2007 PM_{10} Plan and the supporting documentation for the revised budgets are from: (1) New or revised CARB mobile source measures (*e.g.,* heavy-duty truck retrofit requirements and new or revised emissions standards for transportation refrigeration units, portable diesel engines, and large spark ignition engine regulation, among other categories) and new or revised San Joaquin Valley Air Pollution Control District (SJVAPCD or "District") stationary and area source measures (*e.g.,* regulations affecting open burning; boilers, steam generators and process heaters; dryers, dehydrators and ovens; and internal combustion engines, among others); (2) corrections to the Manufacturing and Industrial and Food and Agriculture categories; (3) updates to agricultural and managed burned acreage and the reclassification of Wildfire Use as a natural source category; and (4) updates to CARB's emission estimation models for locomotives, commercial and recreational boats, transportation refrigeration units, construction equipment, oil drilling and workover equipment, cargo handling equipment, and farm equipment.

Table 9 shows that CARB's current estimates of NO_X emissions for 2020 differ substantially from those projected in the 2007 PM_{10} Plan. The changes in growth and control strategy assumptions for non-motor vehicle sources do not change the overall conclusions of the 2007 PM_{10} Plan because they reflect, among other things, additional controls that support continued maintenance of the PM_{10} standard in the SJV beyond those assumed in the plan. While the changes in emissions estimates lend support to the conclusion that the 2007 PM_{10} Plan, with the revised budget, continues to meet the underlying purpose of the plan, *i.e.,* to provide for maintenance of the PM_{10} standard through 2020, the EPA also reviewed the ambient PM_{10} concentration data collected over the past several years in the SJV to see if they too are consistent with the continued maintenance of the standard.

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[20] The direct PM_{10} budgets include PM_{10} emissions from paved road dust, unpaved road dust, and road construction dust, as well as PM_{10} from vehicle exhaust and brake and tire wear.

[21] The 2007 PM_{10} Plan estimated a reduction in stationary source emissions of NO_X from 106 tpd to 103 ptd from 2005 to 2020. See CARB's staff report titled "Analysis of the San Joaquin Valley 2007 PM_{10} Maintenance Plan," appendix B. Instead, controls on such sources, as well as corrections and updates to inventory methods, are now expected to reduce such emissions 30 tpd.

TABLE 9—COMPARISON OF 2020 PM_{10} AND NO_X EMISSIONS REDUCTIONS ASSOCIATED WITH CURRENT AND REVISED BUDGETS FOR THE PM_{10} STANDARD

[Annual average tons per day][22]

Inventory category	2020 Emissions inventory in approved PM_{10} plan		Updated 2020 emissions inventory		Net change	
	Direct PM_{10}	NO_X	Direct PM_{10}	NO_X	Direct PM_{10}	NO_X
Stationary	26.4	103.7	15.3	29.5	−11.1	−74.2
Area	247.8	17.1	251.7	8.4	+3.9	−8.7
On-road	9.7	124.7	7.6	96.7	−2.1	−28.0
Non-road	6.1	82.4	5.6	72.2	−0.5	−10.2
Totals	290.0	327.8	280.2	206.8	−10.2	−121.0

Note: For the net change, a negative number indicates a reduction, and a positive number indicates an increase relative to the corresponding figure in the 2007 PM_{10} Plan.

From our review of the available, quality-assured, and certified PM_{10} ambient air monitoring data in the EPA's Air Quality System (AQS) for 2013 and 2014, along with preliminary data for 2015, we determined that the SJV PM_{10} maintenance area experienced multiple exceedances of the PM_{10} standard in 2013 and 2014. In response to the exceedances, the EPA evaluated whether the District implemented the contingency plan in its 2007 PM_{10} Plan. In its contingency plan, the District established an action level of 155 µg/m³ of PM_{10} over a 24-hour period. Should the action level be reached, the District committed to evaluating the exceedance and take appropriate action within 18 months of the event date. The following major steps comprise the District's contingency plan:

Step 1. The District will examine the event and determine if it needs to be classified as a natural or exceptional event in accordance with the EPA's final rulemaking (72 FR 13560). If the data qualify for flagging under this rule, the District would proceed with preparing and submitting the necessary documentation for a natural/exceptional event, and would not consider the monitored level as a trigger for the maintenance plan contingency plan.

Step 2. If the event does not qualify as a natural or exceptional event, the District would then analyze the event to determine its possible causes. It would examine emission reductions from adopted rules or rule commitments in adopted and approved plans to see if emission reductions not used in demonstrating maintenance of the PM_{10} NAAQS would address the violation.

Step 3. If reductions from Step 2 above are insufficient, the District would proceed with identifying control measures from any feasibility studies (*e.g.*, from the 2007 Ozone Plan) completed to date that recommend future controls and prioritize development of the measures most relevant to reducing PM_{10} levels.

In a March 11, 2016 letter to the EPA,[23] the District summarized the steps they had taken in response to the PM_{10} exceedances, including implementation of the contingency plan in their 2007 PM_{10} Plan. Specifically, the District identified seventeen exceedances of the PM_{10} standard that occurred at five monitoring sites. Of these, the District characterized ten exceedances as high wind events that qualify as exceptional events per criteria in 40 CFR 50.1(j). CARB indicated they will be submitting to the EPA exceptional event documentation for some or all of these events; however, the EPA has not yet received the documentation in support of determining whether the ten exceedances qualify as exceptional events. The District characterized the remaining seven exceedances as exceptional events caused by "exceptional drought conditions" coinciding with stagnant air conditions, and indicated they will be submitting to CARB exceptional event documentation for these events. On February 16, 2016, the District requested that CARB flag five exceedances in AQS as possible exceptional events caused by the drought conditions.[24] On March 10, 2016, CARB responded to the District's February 16, 2016 request and indicated that the five exceedances could not be flagged as exceptional events because they did not meet the definition of an exceptional event in 40 CFR 50.1(j).[25]

In their March 11, 2016 letter to the EPA, the District identified multiple rules and regulations that reduce PM_{10} or PM_{10} precursors beyond commitments in the 2007 PM_{10} Plan. Based on our analysis of the March 11 letter, the EPA has determined there is uncertainty regarding whether the rules and regulations identified by the District, when combined with the PM_{10} revised budgets, are sufficient for maintenance of the PM_{10} standard. Under section 110(k)(4) of the Act, the EPA may conditionally approve a plan revision based on a commitment by the State to adopt specific enforceable measures by a date certain but not later than one year after the EPA approval of the plan or plan revision. In this instance, the District indicated in their March 11, 2016 letter that adequate measures have been adopted to provide continued maintenance of the PM_{10} standard; however, the EPA has determined that the State's revised budgets submittal and the District's March 11, 2016 letter alone are not sufficient for the EPA to determine the area will maintain the 24-hour PM_{10} standard. To help remedy this situation, in an April 29, 2016 letter to the EPA, CARB committed to submit a SIP revision by June 1, 2017 that will provide additional documentation on the nature and causes of each of the recent PM_{10} exceedances. To the extent that data is available, the State committed to the following:[26]

- Evaluation of PM_{10} filter-based and continuous data across the SJV to understand the local or regional nature of each exceedance;

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[22] The 2020 emissions inventory in the approved 2007 PM_{10} Plan is from CARB's Staff Report titled "Analysis of the San Joaquin Valley 2007 PM_{10} Maintenance Plan," appendix B, which was approved as part of the 2007 PM_{10} Plan. See 40 CFR 52.220(c)(356)(ii)(A)(2). The updated 2020 emissions inventory is attached to a December 15, 2015 email from Dennis Wade, CARB, to John Ungvarsky, EPA Region 9.

[23] Letter, Samir Sheikh, Deputy Air Pollution Control Officer, SJVAPCD, to Jared Blumenfeld, Regional Administrator, EPA Region 9, March 11, 2016.

[24] Email, Shawn Ferreria, SJVAPCD, to Theresa Najita, CARB, February 16, 2016.

[25] Email, Theresa Najita, CARB, to Shawn Ferreria, SJVAPCD, March 10, 2016.

[26] For additional background on the District's response to the 2013–2014 PM_{10} exceedances and the State's April 29, 2016 letter, please see the docket for today's action.

- Analysis of $PM_{2.5}$ data to determine whether fine or coarse particles are contributing to the exceedance;
- Analysis of available chemical speciation data including additional filter speciation analysis as appropriate to assess potential source types contributing to each exceedance; and
- Analysis of wind speed and direction, along with geographic visualization tools to help identify the types of sources impacting each monitor.

Based on these analyses, CARB and the District will determine the appropriate remedy to address the nature of each exceedance. This may include submittal of documentation for exceptional events, or analysis and evaluation of the further emission reductions that will accrue from ongoing implementation of current control programs or development of new control measures as part of upcoming attainment plans.

For exceedances that qualify as natural or exceptional events, CARB and the District will follow the notification and data flagging process that is contained in the EPA's revised Exceptional Event Rule ("EE Rule"). This will include a commitment to notify the EPA by July 1 of each year of the PM_{10} data that has been flagged. Subsequent submittal of documentation for each event will follow requirements specified in the EE Rule. In addition, CARB and the District commit to ensuring ongoing network adequacy and data completeness through existing mechanisms such as data certification and the annual network plan review.

Based on the 2020 revised direct PM_{10} and NO_X budgets in table 8 above, the updated inventory estimates in table 9 above, and the commitments in CARB's April 29, 2016 letter, the EPA concludes that a conditional approval of the 2020 revised direct PM_{10} and NO_X budgets supports continued maintenance of the PM_{10} standard and is consistent with applicable CAA requirements; thus, we propose to conditionally approve the 2020 revised direct PM_{10} and NO_X budgets as a revision to the 2007 PM_{10} Plan.[27] If we finalize this proposed conditional approval, CARB must adopt and submit the SIP revisions it has committed to submit by June 1, 2017. If CARB fails to comply with this commitment, the conditional approval will convert to a disapproval.

Lastly, approval of the revised budgets would not affect the trading mechanism first included in the SJV Amended 2003 PM_{10} Plan and approved by the EPA at 69 FR 30006 (May 26, 2004) and later carried forward and approved as part of the 2007 PM_{10} Plan. See pages 20–21 of the 2007 PM_{10} Plan; 73 FR 22307, at 22317 (April 25, 2008); and 73 FR 66759, at 66772 (November 12, 2008). That is, the trading mechanism approved as part of the 2007 PM_{10} Plan will remain available regardless of our action on the revised budgets.

VI. Proposed Action and Request for Public Comment

For the reasons discussed above, the EPA is proposing to approve the revised ozone and $PM_{2.5}$ budgets and conditionally approve the revised PM_{10} budgets in California's November 13, 2015 submittal for the SJV area. The revised budgets are shown in table 1 and are based on estimates from California's EMFAC2014 model.

More specifically, under CAA section 110(k)(3), the EPA is proposing to approve the revised VOC and NO_X budgets for 2017, 2020, and 2023 for the 1997 8-hour ozone standard because replacement of the current approved budgets with the revised budgets would not interfere with the approved RFP and attainment demonstrations for the 1997 8-hour ozone standard in the SJV and because emissions changes in non-motor vehicle emissions categories do not change the overall conclusions of the 2007 Ozone Plan.

Second, the EPA is also proposing to approve the revised direct $PM_{2.5}$ and NO_X budgets for 2017 for the 2006 24-hour $PM_{2.5}$ standard because replacement of the current adequate budgets with the revised budgets would be consistent with our separate proposal finding that the 2012 $PM_{2.5}$ Plan demonstrates RFP for year 2017, because emissions changes in non-motor vehicle emissions categories do not change the overall conclusion of the 2012 $PM_{2.5}$ Plan, and because the revised budgets meet the adequacy criteria in 40 CFR 93.118(e)(4)(i)–(vi).

Third, under CAA section 110(k)(4), the EPA is proposing to conditionally approve the revised direct PM_{10} and NO_X budgets for 2020 for the 24-hour PM_{10} standard because, when combined with implementation of the contingency plan in the SIP-approved 2007 PM_{10} Plan and fulfillment of the commitments in the State's April 29, 2016 letter, they will allow the SJV to continue to demonstrate maintenance of the 24-hour PM_{10} standard. If we finalize this proposed conditional approval, CARB must adopt and submit the SIP revisions that it has committed to submit by June 1, 2017. If CARB fails to comply with this commitment, the conditional approval will convert to a disapproval. Disapproval of the revised budgets for the 2007 PM_{10} Plan would reinstate the existing approved budgets as the budgets that must be used in transportation plan and TIP conformity determinations after the effective date of the disapproval. See 40 CFR 93.109(c)(1). Because the submittal of the revised budgets is not a required submittal, disapproval would not trigger sanctions under CAA section 179(a)(2) but would nonetheless trigger a two-year clock for a federal implementation plan under CAA section 110(c), and it would not trigger a transportation conformity freeze because the disapproval does not affect a control strategy implementation plan as defined in the transportation conformity rule. See 40 CFR 93.101 and 93.120(a).

Lastly, if the EPA takes final action to approve the revised budgets as proposed, the San Joaquin Valley MPOs and DOT must use the revised budgets for future transportation conformity determinations.

The EPA is soliciting public comments on the issues discussed in this document or on other relevant matters. We will accept comments from the public on this proposal for the next 30 days. We will consider these comments before taking final action.

VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve State choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve a state plan as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under

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[27] To comply with CAA section 175A(a), a maintenance plan must provide for the maintenance of standard (for which an area is being redesignated) for 10 years from redesignation to attainment, under CAA section 175A(b), states are required, within eight years of redesignation to attainment, to submit a revision to the SIP that provides for the maintenance of the standard an additional ten years after expiration of the initial 10-year period. For the SJV and PM_{10}, California must submit a subsequent 10-year maintenance plan by December 12, 2016. We expect that the subsequent SJV PM_{10} maintenance plan will address the recent exceedances described in today's action.

Executive Order 12866 (58 FR 51735, October 4, 1993);

- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires the EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have Tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes."

Eight Indian tribes are located within the boundaries of the San Joaquin Valley air quality planning area for the 1997 8-hour ozone, 2006 24-hour PM$_{2.5}$, and 1987 24-hour PM$_{10}$ standards: the Big Sandy Rancheria of Mono Indians of California, the Cold Springs Rancheria of Mono Indians of California, the North Fork Rancheria of Mono Indians of California, the Picayune Rancheria of Chukchansi Indians of California, the Santa Rosa Rancheria of the Tachi Yokut Tribe, the Table Mountain Rancheria of California, the Tejon Indian Tribe, and the Tule River Indian Tribe of the Tule River Reservation.

The EPA's proposed approval of the revised budgets submitted by CARB to address the 1997 8-hour ozone, 2006 24-hour PM$_{2.5}$, and 1987 24-hour PM$_{10}$ standards in the San Joaquin Valley would not have tribal implications because the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed SIP approvals do not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). Therefore, the EPA has concluded that the proposed action will not have tribal implications for the purposes of Executive Order 13175, and would not impose substantial direct costs upon the tribes, nor would it preempt Tribal law. We note that none of the tribes located in the San Joaquin Valley has requested eligibility to administer programs under the CAA.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental regulations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: May 9, 2016.

Deborah Jordan,

Acting Regional Administrator, EPA Region 9.

[FR Doc. 2016–11741 Filed 5–17–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA–HQ–OAR–2015–0663; FRL–9946–50–OAR]

RIN 2060–AS80

Protection of Stratospheric Ozone: Proposed New Listings of Substitutes; Changes of Listing Status; and Reinterpretation of Unacceptability for Closed Cell Foam Products Under the Significant New Alternatives Policy Program; and Revision of Clean Air Act Section 608 Venting Prohibition for Propane

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking; extension of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing that the period for providing public comments on the April 18, 2016, proposed "Protection of Stratospheric Ozone: Proposed New Listings of Substitutes; Changes of Listing Status; and Reinterpretation of Unacceptability for Closed Cell Foam Products under the Significant New Alternatives Policy Program; and Revision of Clean Air Act Section 608 Venting Prohibition for Propane" is being extended by 14 days.

DATES: *Comments.* The public comment period for the proposed rule, which published April 18, 2016, (81 FR 22810) is being extended by 14 days and will close on June 16, 2016. This extension provides the public additional time to submit comments and supporting information.

ADDRESSES: *Comments.* Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2015–0663, to the *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Chenise Farquharson, Stratospheric Protection Division, Office of Atmospheric Programs (Mail Code 6205 T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202–564–7768; email address: *Farquharson.chenise@epa.gov.* Notices and rulemakings under EPA's Significant New Alternatives Policy program are available on EPA's Stratospheric Ozone Web site at *https://www.epa.gov/snap/snap-regulations.*

SUPPLEMENTARY INFORMATION:

Comment Period

The EPA is extending the public comment period for the proposed rule (81 FR 22810; April 18, 2016) an additional 14 days. The public comment period will end on June 16, 2016, rather than June 2, 2016. This will provide the public additional time to review and comment on all of the information available, including the proposed rule and other materials in the docket.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Recycling, Reporting and recordkeeping requirements, Stratospheric ozone layer.

Dated: May 11, 2016.

Sarah Dunham,

Director, Office of Atmospheric Programs.

[FR Doc. 2016–11627 Filed 5–17–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 74

[MB Docket Nos. 07–294 and 10–103, MD Docket No. 10–234; Report No. 3043]

Petitions for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petitions for reconsideration.

SUMMARY: Petitions for Reconsideration (Petitions) have been filed in the Commission's rulemaking proceeding by: Lawrence M. Miller, on behalf of Public Broadcasting Parties, Sylvia Strobel, on behalf of American Public Media Group, Todd D. Gray, on behalf of NCE Licensees and Joseph B. Porter, on behalf of The State University of New York.

DATES: Oppositions to the Petitions must be filed on or before June 2, 2016. Replies to an opposition must be filed on or before June 13, 2016.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jessica Campbell, Media Bureau, (202) 418–3609, email: *jessica.campbell@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of Commission's document, Report No. 3043, released May 9, 2016. The full text of the Petitions is available for viewing and copying at the FCC Reference Information Center, 445 12th Street SW., Room CY–A257, Washington, DC 20554 or may be accessed online via the Commission's Electronic Comment Filing System at *http://apps.fcc.gov/ecfs/.* The Commission will not send a copy of this *Public Notice* pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A), because this *Public Notice* does not have an impact on any rules of particular applicability.

Subject: Promoting Diversification of Ownership in the Broadcasting Services, published at 81 FR 19432, April 4, 2016, in MB Docket Nos. 07–294 and 10–103, MD Docket No. 10–234, and FCC 16–1. This *Public Notice* is being published pursuant to 47 CFR 1.429(e). *See also* 47 CFR 1.4(b)(1).

Number of Petitions Filed: 4

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2016–11689 Filed 5–17–16; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 81, No. 96
Wednesday, May 18, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

USDA Increases the Fiscal Year 2016 Raw Sugar Tariff-Rate Quota

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: The Office of the Secretary of the Department of Agriculture is providing notice of an increase in the fiscal year (FY) 2016 raw cane sugar tariff-rate quota (TRQ) of 127,006 metric tons raw value (MTRV).

DATES: Effective May 18, 2016.

FOR FURTHER INFORMATION CONTACT: Souleymane Diaby, Import Policies and Export Reporting Division, Foreign Agricultural Service, Stop 1021, U.S. Department of Agriculture, Washington, DC 20250–1021; or by telephone (202) 720–2916; or by fax to (202) 720–8461; or by email to *Souleymane.Diaby@fas.usda.gov*.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of the Department of Agriculture is providing notice of an increase in the fiscal year (FY) 2016 (October 1, 2015-September 30, 2016) raw cane sugar tariff-rate quota (TRQ) of 127,006 metric tons raw value (MTRV). On June 15, 2015, the Office of the Secretary established the FY 2016 TRQ for raw cane sugar at 1,117,195 MTRV (1,231,497 short tons raw value, STRV *), the minimum to which the United States is committed under the World Trade Organization (WTO) Uruguay Round Agreements. (80 FR 34129). Pursuant to Additional U.S. Note 5 to Chapter 17 of the U.S. Harmonized Tariff Schedule (HTS) and Section 359k of the Agricultural Adjustment Act of 1938, as amended, the Secretary of Agriculture gives notice of an increase in the quantity of raw cane sugar eligible to enter at the lower rate of duty during FY 2016 by 127,006 MTRV (140,000 STRV). With this increase, the overall FY 2016 raw sugar TRQ is now 1,244,201 MTRV (1,371,497 STRV). Raw cane sugar under this quota must be accompanied by a certificate for quota eligibility and may be entered until September 30, 2016. The Office of the U.S. Trade Representative will allocate this increase among supplying countries and customs areas.

This action is being taken after a determination that additional supplies of raw cane sugar are required in the U.S. market. USDA will closely monitor stocks, consumption, imports and all sugar market and program variables on an ongoing basis, and may make further program adjustments during FY 2016 if needed.

Dated: May 13, 2016.

Alexis M. Taylor,

Deputy Under Secretary, Farm and Foreign Agricultural Services.

[FR Doc. 2016–11732 Filed 5–17–16; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

Solicitation of Commodity Board Topics and Contribution of Funding Under the Agriculture and Food Research Initiative Competitive Grants Program

AGENCY: National Institute of Food and Agriculture, USDA.

ACTION: Notice of opportunity for commodity boards to submit topics and contribute funding under the Agriculture and Food Research Initiative Competitive Grants Program.

SUMMARY: As part of the National Institute of Food and Agriculture's (NIFA) strategy to implement section 7404 of Public Law 113–79, the Agricultural Act of 2014, NIFA is soliciting topics from eligible commodity board entities (Federal and State-level commodity boards, as defined below) which they are willing to equally co-fund with NIFA. Such topics must relate to the established priority areas of the Agriculture and Food Research Initiative Competitive Grants Program (AFRI) to be considered for inclusion in future AFRI Requests for Applications (RFAs).

Commodity boards are those entities established under a commodity promotion law (as such term is defined under section 501(a) of the Federal Agriculture Improvement and Reform Act of 1996 (7 U.S.C. 7401(a)) or a State commodity board (or other equivalent State entity). *See* the "Supplementary Information" section of this Notice under the heading "Eligibility for Submitting Topics" for further information.

If proposed topics are accepted for inclusion in an AFRI RFA after evaluation by NIFA, they will be incorporated into AFRI competitive grants program RFAs. As a condition of funding grants in a topic, NIFA will require an agreement with the commodity board to provide funds that are equal to the amount NIFA is contributing under the agreed upon topic.

This Notice invites topic submissions from commodity boards as defined above, outlines the process NIFA will use to evaluate the appropriateness of these topics for inclusion in AFRI RFAs, and describes the commitment commodity boards will be required to make in order for NIFA to jointly fund AFRI applications competitively selected for award within a topic area submitted by the commodity boards.

DATES: Topics may be submitted by commodity boards at any time; however, all topics to be considered for the fiscal year 2017 AFRI RFAs must be received by 5:00 p.m., EDT on July 18, 2016. Topics submitted by eligible commodity board entities after this date will be considered for RFAs to be issued in future years. NIFA will hold a webinar and workshop to respond to questions from commodity boards interested in submitting topics. Details including the date and time, and access information will be posted on the NIFA Web site (*http://nifa.usda.gov/commodity-boards/*).

ADDRESSES: You may submit topics, identified by NIFA–2016–0001, by the following method:

Email: commodityboards@nifa.usda.gov.

Instructions: Include NIFA–2016–0001 in the subject line of the message. The topic submission must be attached to the email using the template located at *http://nifa.usda.gov/commodity-boards/*. All topics received must include the agency name and reference to NIFA–2016–0001. Topics submitted by email will not be posted to a public site.

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* Conversion factor: 1 metric ton = 1.10231125 short tons.

FOR FURTHER INFORMATION CONTACT: Mark Mirando; Phone: (202) 401–4336, or Robert Hedberg; Phone: (202) 720–5384, or Email: *commodityboards@nifa.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

This Notice begins the second topic submission cycle to implement section 7404 of the Agricultural Act of 2014, Public Law 113–79, which amends section 2(b) of the Competitive, Special, and Facilities Research Grant Act (7 U.S.C. 450i(b)) to require that NIFA "establish procedures, including timelines, under which an entity established under a commodity promotion law (as such term is defined under section 501(a) of the Federal Agriculture Improvement and Reform Act of 1996 (7 U.S.C. 7401(a)) or a State commodity board (or other equivalent State entity) may directly submit to the Secretary [(NIFA)] for consideration proposals for requests for applications . . ." within the AFRI Program.

Stakeholder feedback gathered as a result of the September 2014 Notice and during the initial year of implementation (in fiscal year 2016) informed this Notice and the process NIFA is using to implement section 7404. This Notice invites entities established under a commodity promotion law or State commodity boards (or other equivalent State entities) to submit topics which they are proposing for inclusion in upcoming AFRI RFAs in fiscal year 2017. Topics must relate to the established AFRI priority areas, which are plant health and production and plant products; animal health and production and animal products; food safety, nutrition, and health; bioenergy, natural resources, and environment; agriculture systems and technology; and agriculture economics and rural communities. A summary statement on AFRI is included below. To learn more about AFRI programs, including program priorities, typical award budget amounts, and examples of RFAs, please visit: *http://nifa.usda.gov/commodity-boards.*

AFRI Program Overview

The AFRI program is the largest agricultural competitive grants program in the United States and a primary funding source for research, education, and extension projects that bring practical solutions to some of today's most critical societal challenges. AFRI programs impact all components of agriculture, including farm and ranch efficiency and profitability, bioenergy, forestry, aquaculture, rural communities, human nutrition, food safety, biotechnology, and genetic improvement of plants and animals.

In FY 2017, NIFA will issue at least seven AFRI RFAs to solicit applications in the six statutory priority areas in AFRI (Plant health and production and plant products; Animal health and production and animal products; Food safety, nutrition, and health; Bioenergy, natural resources, and environment; Agriculture systems and technology; Agriculture economics and rural communities). It is anticipated that these will include five Challenge Area RFAs, which address the following major societal challenges: Sustainable Bioenergy; Climate Variability and Change; Water for Food Production Systems; Childhood Obesity Prevention; and Food Safety. The Challenge Area RFAs solicit grant applications for focused problem-solving efforts and provide large awards (typically $1 million or more) for periods of up to 5 years to enable collaboration among multiple organizations and the integration of research with education and/or extension. The sixth RFA is the Foundational Program RFA issued annually which solicits grant applications that focus predominately, but not exclusively, on fundamental scientific research that addresses statutory priorities. The final RFA is the AFRI Food, Agriculture, Natural Resources, and Human Sciences Education and Literacy Initiative (ELI) RFA which solicits grant applications for undergraduate research and extension experiential learning fellowships, and pre- and post-doctoral fellowships.

Eligibility for Submitting Topics

Eligible commodity board entities are those established under a commodity promotion law (as such term is defined under section 501(a) of the Federal Agriculture Improvement and Reform Act of 1996 (7 U.S.C. 7401(a))) or a State commodity board (or other equivalent State entity). Language in 7 U.S.C. 7401(a) defines a "commodity promotion law" as "a Federal law that provides for the establishment and operation of a promotion program regarding an agricultural commodity that includes a combination of promotion, research, industry information, or consumer information activities, is funded by mandatory assessments on producers or processors, and is designed to maintain or expand markets and uses for the commodity (as determined by the Secretary)." Section 7401(a) includes a list of such Federal laws.

A current list of approved entities is maintained at (*http://nifa.usda.gov/commodity-boards*). Additionally, entities eligible to submit topics include a State commodity board (or other equivalent State entity). This includes commodity boards authorized by State law; commodity boards that are not authorized by State law but are organized and operate within a State and meet the requirements of their authorizing statute; and commodity boards that are authorized by a State and operate within the State for commodities that have no Federal program or oversight.

Topic Submission Guidance and Procedures

Topics may be submitted at any time and will be evaluated by NIFA on an annual basis. However, to be considered for the proposed fiscal year 2017 AFRI RFAs, topics must be received by COB (5 p.m. Eastern Daylight Time) on July 18, 2016.

Each topic proposed must be submitted using the template provided at: *http://nifa.usda.gov/commodity-boards.* Commodity boards may propose support for multiple awards for each topic proposed. For each topic the commodity board proposes to support, the minimum amount contributed by the commodity board must align with budget guidance for each AFRI area (*http://nifa.usda.gov/commodity-boards*) and comply with the maximum amount of $2.5 million allowed per topic. NIFA does not intend to match funding from a single commodity board in excess of $10 million in any year. Commodity boards should only submit topics that have a strong economic impact on their industry and U.S. agriculture as a whole. Examples of topics typically supported by AFRI can be found at *http://nifa.usda.gov/commodity-boards.*

If topics are accepted for funding, they will be incorporated into AFRI RFAs, and grants supporting the topic area may be awarded to AFRI eligible entities based on a competitive peer review process. As a condition of funding grants in a topic, NIFA will require an agreement to provide funds by the commodity board that is equal to the amount NIFA is contributing under the agreed upon topic. If a topic is selected for inclusion in an RFA, the commodity board submitting the topic will be required to maintain the confidentiality of the topic until the RFA is issued by NIFA. Commodity board funds must be made available to NIFA no later than the time awards are selected for funding. The grants will be fully funded at the beginning of the award, thus requiring that all commodity board funds and NIFA funds be available at the time of the award. Applications submitted under topics provided by commodity boards will be required to include a letter of support from the commodity board that proposed the topic.

Evaluation and Notification Process

NIFA will screen proposed research topics to ensure they were submitted by eligible commodity boards and consult with USDA's Agricultural Marketing Service (AMS) to determine that submissions and proposed financial contributions are consistent with commodity promotion laws and commodity boards' charters as applicable.

Commodity board topics will be reviewed by an internal panel based on evaluation criteria that were developed using stakeholder input from commodity boards and other stakeholders from government, industry, and academe. Each topic will be evaluated based on: Alignment with one or more of the statutory AFRI priority areas (six AFRI priority areas authorized in the Farm Bill and described in 7 CFR 3430.309); alignment with the President's budget proposal for NIFA, as identified in the Department of Agriculture's annual budget submission; and alignment with the priority areas in the AFRI RFAs to be released by NIFA during the fiscal year for which the commodity board is proposing a topic for funding (for example, within the AFRI Foundational Program RFA, the AFRI Animal Health and Production and Animal Product's "Animal Reproduction" priority area).

From those topics received by COB (5 p.m. Eastern Daylight Time) on July 18, 2016, NIFA will select the topic(s) that were evaluated favorably for inclusion in the appropriate FY 2017 AFRI RFA. NIFA will notify commodity boards whether their topics will be included by August 16, 2016. Based on the evaluation, NIFA reserves the right to negotiate with commodity boards should changes be required for topics and funding amounts to be accepted. Any changes to topics and funding amounts will be reviewed by USDA's AMS to determine if such changes are consistent with applicable commodity promotion laws.

NIFA will evaluate topics submitted after the July 18, 2016 deadline on an annual basis and notify commodity boards whether their topics will be included in subsequent RFAs within two weeks following the meeting of the internal evaluation panel, the date of which will be published on NIFA's Commodity Boards Web page at (*http://nifa.usda.gov/commodity-boards/*).

Done at Washington, DC this 12th day of May, 2016.

Sonny Ramaswamy,

Director, National Institute of Food and Agriculture.

[FR Doc. 2016–11705 Filed 5–17–16; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–35–2016]

Foreign-Trade Zone 244—Riverside, California; Application for Reorganization; (Expansion of Service Area); Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the March Joint Powers Authority, grantee of Foreign-Trade Zone 244, requesting authority to reorganize the zone to expand its service area under the alternative site framework (ASF) adopted by the FTZ Board (15 CFR Sec. 400.2(c)). The ASF is an option for grantees for the establishment or reorganization of zones and can permit significantly greater flexibility in the designation of new subzones or "usage-driven" FTZ sites for operators/users located within a grantee's "service area" in the context of the FTZ Board's standard 2,000-acre activation limit for a zone. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on May 12, 2016.

FTZ 244 was approved by the FTZ Board on August 21, 2000 (Board Order 1104, 65 FR 54196, September 7, 2000) and reorganized under the ASF on May 13, 2011 (Board Order 1761, 76 FR 29725, May 23, 2011). The zone currently has a service area that includes western Riverside County, California.

The applicant is now requesting authority to expand the service area of the zone to include the City of Lake Elsinore, as described in the application. If approved, the grantee would be able to serve sites throughout the expanded service area based on companies' needs for FTZ designation. The application indicates that the proposed expanded service area is adjacent to the Los Angeles/Long Beach U.S. Customs and Border Protection Port of Entry.

In accordance with the FTZ Board's regulations, Christopher Kemp of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is July 18, 2016. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to August 1, 2016.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the "Reading Room" section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz*. For further information, contact Christopher Kemp at *Christopher.Kemp@trade.gov* or (202) 482–0862.

Dated: May 12, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–11739 Filed 5–17–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–838]

Certain Frozen Warmwater Shrimp From Brazil: Rescission of Antidumping Duty Administrative Review; 2015–2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is rescinding the administrative review of the antidumping duty order on certain frozen warmwater shrimp from Brazil for the period February 1, 2015, through January 31, 2016.

DATES: Effective May 18, 2016.

FOR FURTHER INFORMATION CONTACT: Kate Johnson or Terre Keaton Stefanova, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202)

482–4929 or (202) 482–1280, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 3, 2016, the Department published in the **Federal Register** a notice of "Opportunity to Request Administrative Review" of the antidumping duty order on certain frozen warmwater shrimp from Brazil for the period of February 1, 2015, through January 31, 2016.[1]

On February 24, 2016, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b), the Department received a timely request from the Ad Hoc Shrimp Trade Action Committee (the petitioner),[2] a domestic interested party, to conduct an administrative review of the sales of Amazonas Industrias Alimenticias S.A. (AMASA). The petitioner was the only party to request this administrative review.

On April 7, 2016, the Department published in the **Federal Register** a notice of initiation of an administrative review of the antidumping duty order on certain warmwater shrimp from Brazil with respect to AMASA.[3]

On April 11, 2016, the petitioner timely withdrew its request for a review of AMASA.[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if a party that requested a review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review. The petitioner timely withdrew its request for review before the 90-day deadline, and no other party requested an administrative review of the antidumping duty order. Therefore, we are rescinding the administrative review of the antidumping duty order on certain frozen warmwater shrimp from Brazil covering the period February 1, 2015, through January 31, 2016.

Assessment

The Department will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions directly to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as the only reminder to importers of their responsibility, under 19 CFR 351.402(f)(2), to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement may result in the presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This notice is published in accordance with section 751 of the Act and 19 CFR 351.213(d)(4).

Dated: May 10, 2016.

Gary Taverman,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–11664 Filed 5–17–16; 8:45 am]

BILLING CODE 3510–DS–P

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[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review*, 81 FR 5712 (February 3, 2016).

[2] The Ad Hoc Shrimp Trade Action Committee's members are: Nancy Edens; Papa Rod, Inc.; Carolina Seafoods; Bosarge Boats, Inc.; Knight's Seafood Inc.; Big Grapes, Inc.; Versaggi Shrimp Co.; and Craig Wallis.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 81 FR 20324 (April 7, 2016).

[4] *See* petitioner's letter, "Certain Frozen Warmwater Shrimp from Brazil: Withdrawal of Request for Administrative Review," dated April 11, 2016.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–968]

Aluminum Extrusions From the People's Republic of China: Notice of Correction to Amended Final Results of Countervailing Duty Administrative Review; 2013

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Davina Friedmann, Tyler Weinhold or Robert James, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0698, (202) 482–1121 or (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION: On March 22, 2016, the Department of Commerce (the Department) published the *Amended Final Results* of the administrative review of the countervailing duty (CVD) order[1] on aluminum extrusions from the People's Republic of China (PRC) for the January 1, 2013, through December 31, 2013 period of review (POR).[2] The *Amended Final Results* contained an inadvertent error. Specifically, we referenced CVD case number "C–570–068" at the head of the notice. The correct CVD case number is "C–570–968." As a result, we now correct the *Amended Final Results* as noted above.

This correction to the *Amended Final Results* is issued and published in accordance with section 777(i)(1) of the Tariff Act of 1930, as amended.

Dated: May 9, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–11735 Filed 5–17–16; 8:45 am]

BILLING CODE 3510–DS–P

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[1] *See Aluminum Extrusions from the People's Republic of China: Countervailing Duty Order*, 76 FR 30653 (May 26, 2011) (*Order*).

[2] *See Aluminum Extrusions from the People's Republic of China: Amended Final Results of Countervailing Duty Administrative Review; 2013*, 81 FR 15238 (March 22, 2016) (*Amended Final Results*).

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. Sec. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, CNCS is soliciting comments concerning its proposed use of the AmeriCorps NCCC Medical/Mental Health Information Form. An individual must have the physical and mental capacity required to perform the essential functions of the AmeriCorps NCCC member position, with or without reasonable accommodation, for which he or she is otherwise eligible.

Copies of the information collection request can be obtained by contacting the office listed in the Addresses section of this Notice.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by July 18, 2016.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail sent to: Corporation for National and Community Service, AmeriCorps NCCC; Attention Tara Lind-Zajac, Lead Medical Nurse, 3237–Q; 250 E Street SW., Washington, DC 20525.

(2) By hand delivery or by courier to the CNCS mailroom at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) Electronically through *www.regulations.gov.*

Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Tara Lind-Zajac, 202–360–8082, or by email at *TLindZajac@cns.gov.*

SUPPLEMENTARY INFORMATION:

CNCS is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are expected to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submissions of responses).

Background

An individual must have the physical and mental capacity required to perform the essential functions of the AmeriCorps lNCCC member position, with or without reasonable accommodation, for which he or she is otherwise eligible. Individuals applying to the AmeriCorps NCCC program provide the information collected on this form in order to be cleared to participate in the program.

Current Action

This is a new information collection request. The Medical/Mental Health Information Form is completed at the time individuals complete the AmeriCorps NCCC program application. This allows individuals to submit a "complete" application to AmeriCorps NCCC, allowing a shortened and simplified application/review/clearance process. The Medical/Mental Health Information Form is not reviewed until after an applicant receives a conditional invitation to participate in the AmeriCorps NCCC program. Forms are submitted via pre-addressed, tracked, UPS envelopes included with the mailings in which applicants receive the blank forms.

Type of Review: New.

Agency: Corporation for National and Community Service.

Title: AmeriCorps NCCC Medical/Mental Health Information Form.

OMB Number: None.

Agency Number: None.

Affected Public: Applicants to AmeriCorps NCCC.

Total Respondents: Approximately 2500/year.

Frequency: Once per completed NCCC application.

Average Time per Response: Averages 15 minutes.

Estimated Total Burden Hours: Approximately 625 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: May 11, 2016.

Charles L. Davenport, Jr.,

Director of Recruitment, Selection and Placement, NCCC.

[FR Doc. 2016–11734 Filed 5–17–16; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Military Family Readiness Council (MFRC); Notice of Federal Advisory Committee Meeting

AGENCY: Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing this notice to announce a Federal advisory committee meeting of the Department of Defense Military Family Readiness Council. This meeting will be open to the public.

DATES: Thursday, June 16, 2016, from 1:00 p.m. to 3:00 p.m.

ADDRESSES: Pentagon Conference Center B6 (escorts will be provided from the Pentagon Metro entrance).

FOR FURTHER INFORMATION CONTACT: Ms. Melody McDonald or Ms. Betsy Graham, Office of the Deputy Assistant Secretary of Defense (Military Community & Family Policy), Office of Family Readiness Policy, 4800 Mark Center Drive, Alexandria, VA 22350–2300, Room 3G15. Telephones (571) 372–0880; (571) 372–0881 and/or email: OSD Pentagon OUSD P–R Mailbox Family Readiness Council, *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil.*

SUPPLEMENTARY INFORMATION:

This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150. The purpose of the Council is to review and make recommendations to the Secretary of Defense regarding policy and plans;

monitor requirements for the support of military family readiness by the Department of Defense; and evaluate and assess the effectiveness of the military family readiness programs and activities of the Department of Defense.

Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public, subject to the availability of space. The process for the public entering the Pentagon has changed. Persons without Pentagon access must submit their Full Name, Full SSN, and Date of Birth by fax at 571–372–0884 or email to *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil,* no later than 5:00 p.m., on Thursday, June 9, 2016 to arrange for escort inside the Pentagon to the Conference Room area. Pursuant to 41 CFR 102–3.105(j) and 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, interested persons may submit a written statement for consideration by the Council. Persons desiring to submit a written statement to the Council must submit to the email address OSD Pentagon OUSD P–R Mailbox Family Readiness Council, *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil,* no later than 5:00 p.m., on Monday, June 6, 2016.

The purpose of this meeting is to receive an update on ongoing items of Council interest, and to determine Military Family Readiness Council focus items for Fiscal Year 2016.

Thursday, June 16, 2016 Meeting Agenda

Welcome & Administrative Remarks

TRICARE for Kids (TFK) Report to Congress: Update from the Office of the Assistant Secretary of Defense for Health Affairs

Financial conditions of military members and their spouses: Survey update from the Defense Manpower and Data Center

Financial Readiness and Force Education: Update from the Office of the Assistant Secretary of Defense for Readiness (Force Education)

Member Discussion and Deliberation

Closing Remarks

Note: Exact order may vary.

Dated: May 13, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–11736 Filed 5–17–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Vietnam War Commemoration Advisory Committee; Notice of Federal Advisory Committee Meeting

AGENCY: DoD.

ACTION: Meeting notice.

SUMMARY: The Department of Defense is publishing this notice to announce the following Federal advisory committee meeting of the Vietnam War Commemoration Advisory Committee. This meeting is open to the public.

DATES: The public meeting of the Vietnam War Commemoration Advisory Committee (hereafter referred to as "the Committee") will be held on Friday, June 3, 2016. The meeting will begin at 1:00 p.m. and end at 4:00 p.m.

ADDRESSES: U.S. Access Board Conference Room, 1331 F Street NW., Suite 1000, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Committee's Designated Federal Officer: The committee's Designated Federal Officer is Mr. Michael Gable, Vietnam War Commemoration Advisory Committee, 241 18th Street South, Arlington VA 22202, *michael.l.gable.civ@mail.mil,* 703–697–4811. For meeting information please contact Mr. Michael Gable, *michael.l.gable.civ@mail.mil,* 703–697–4811; Mr. Mark Franklin, *mark.r.franklin.civ@mail.mil,* 703–697–4849; or Ms. Scherry Chewning, *scherry.l.chewning.civ@mail.mil,* 703–697–4908.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: At this meeting, the Committee will convene and receive a series of updates on the Vietnam War Commemoration. The mission of the Committee is to provide the Secretary of Defense, through the Director of Administration and Management (DA&M), independent advice and recommendations regarding major events and priority of efforts during the commemorative program for the 50th Anniversary of the Vietnam War, in order to achieve the objectives for the Commemorative Program.

Availability of Materials for the Meeting: A copy of the agenda for the Committee may be obtained from the Committee's Web site at *http://vietnamwar50th.com.* Copies will also be available at the meeting.

Meeting Agenda

1:00 p.m.–1:10 p.m. Convene with Committee Chairman Remarks

1:10 p.m.–4:00 p.m. Committee Meeting/Agenda items

- Commemoration Program Update
- Communications Working Group Presentation to Full Federal Advisory Committee
- Deliberation on Communications Working Group Recommendation
- Closing remarks

4:00 p.m. Adjourn

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. All members of the public who wish to attend the public meeting must contact Mr. Michael Gable, Mr. Mark Franklin or Ms. Scherry Chewning at the number listed in the **FOR FURTHER INFORMATION CONTACT** section.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Mr. Michael Gable, Mr. Mark Franklin or Ms. Scherry Chewning at the number listed in the **FOR FURTHER INFORMATION CONTACT** section at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Procedures for Providing Public Comments: Pursuant to 41 CFR 102–3.105(j) and 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written comments to the Committee about its mission and topics pertaining to this public meeting.

Written comments should be received by the DFO at least five (5) business days prior to the meeting date so that the comments may be made available to the Committee for their consideration prior to the meeting. Written comments should be submitted via email to the address for the DFO given in the **FOR FURTHER INFORMATION CONTACT** section in either Adobe Acrobat or Microsoft Word format. Please note that since the Committee operates under the provisions of the Federal Advisory Committee Act, as amended, all submitted comments and public presentations will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the Committee's Web site.

Dated: May 12, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–11666 Filed 5–17–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0061]

Agency Information Collection Activities; Comment Request; 2018 Teaching and Learning International Survey (TALIS 2018) Main Study Recruitment and Field Test

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a reinstatement of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before July 18, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0061. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–105, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kashka Kubzdela at *kashka.kubzdela@ed.gov.*

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: 2018 Teaching and Learning International Survey (TALIS 2018) Main Study Recruitment and Field Test.

OMB Control Number: 1850–0888.

Type of Review: A reinstatement of a previously approved information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 1,228.

Total Estimated Number of Annual Burden Hours: 1,949.

Abstract: The Teaching and Learning International Survey (TALIS) is an international survey of teachers and principals that focuses on the working conditions of teachers and the teaching and learning practices in schools. TALIS was first administered in 2008 and is conducted every five years. Having participated in 2013 but not in 2008, the United States will administer TALIS for the second time in 2018. TALIS is sponsored by the Organization for Economic Cooperation and Development (OECD). In the United States, TALIS is conducted by the National Center for Education Statistics (NCES), of the Institute of Education Sciences within the U.S. Department of Education. TALIS 2018 will address teacher training and professional development, teachers' appraisal, school climate, school leadership, teachers' instructional approaches, and teachers' pedagogical practices. In February 2017, TALIS 2018 field test will be conducted to evaluate newly developed teacher and school questionnaire items and test the survey operations. This request is for recruitment and pre-survey activities for the 2017 field test sample, administration of the field test, and recruitment of schools for the 2018 main study sample.

Dated: May 13, 2016.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–11676 Filed 5–17–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Update on Reimbursement for Costs of Remedial Action at Active Uranium and Thorium Processing Sites

AGENCY: Department of Energy.

ACTION: Notice of the Title X claims during fiscal year (FY) 2016.

SUMMARY: This Notice announces the Department of Energy's (DOE) acceptance of claims in FY 2016 from eligible active uranium and thorium processing site licensees for reimbursement under Title X of the Energy Policy Act of 1992 (Public Law 102–486, as amended). The Consolidated Appropriations Act, 2016 (Public Law 114–113) provided $32,959,000 for Title X uranium and thorium reimbursements to be made available to the Title X licensees on a prorated basis. The FY 2017 Department of Energy Office of Environmental Management's Congressional Budget Request requests $30 million for the Title X Program.

DATES: The closing date for the submission of FY 2016 Title X claims is September 16, 2016. The claims will be processed for payment together with any eligible unpaid approved claim balances from prior years, based on the availability of funds from congressional appropriations. If the total approved claim amounts exceed the available funding, the approved claim amounts will be reimbursed on a prorated basis. All reimbursements are subject to the availability of funds from congressional appropriations.

ADDRESSES: Claims should be forwarded by certified or registered mail, return receipt requested, to U.S. Department of Energy, Office of Legacy Management, Attn: Deborah Barr, Title X Lead for Review of Reimbursement of Claims, U.S. Department of Energy, Office of Legacy Management, 2597 Legacy Way, Grand Junction, Colorado 81503. Two copies of the claim should be included with each submission.

FOR FURTHER INFORMATION CONTACT: Theresa Kliczewski, Title X Program Coordinator, at (202)586–3301, of the U.S. Department of Energy, Office of Environmental Management, Office of Disposition Planning & Policy.

SUPPLEMENTARY INFORMATION: DOE published a final rule under 10 CFR part 765 in the **Federal Register** on May 23, 1994, (59 FR 26714) to carry out the requirements of Title X of the Energy Policy Act of 1992 (sections 1001–1004 of Public Law 102–486, 42 U.S.C. 2296a *et seq.*) and to establish the procedures for eligible licensees to submit claims for reimbursement. DOE amended the final rule on June 3, 2003, (68 FR 32955) to adopt several technical and administrative amendments (*e.g.*, statutory increases in the reimbursement ceilings). Title X requires DOE to reimburse eligible uranium and thorium licensees for certain costs of decontamination, decommissioning, reclamation, and other remedial action incurred by licensees at uranium and thorium processing sites to remediate byproduct material generated resulting from the sales to the United States Government. To be reimbursable, costs of remedial action must be for work that is necessary to comply with applicable requirements of the Uranium Mill Tailings Radiation Control Act of 1978 (42 U.S.C. 7901 *et seq.*) or, where appropriate, with requirements established by a State pursuant to a discontinuance agreement under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021). Claims for reimbursement must be supported by reasonable documentation as determined by DOE in accordance with 10 CFR part 765. Funds for reimbursement will be provided from the Uranium Enrichment Decontamination and Decommissioning Fund established at the Department of Treasury pursuant to section 1801 of the Atomic Energy Act of 1954 (42 U.S.C. 2297g). Payment or obligation of funds shall be subject to the requirements of the Anti-Deficiency Act (31 U.S.C. 1341).

Authority: Section 1001–1004 of Public Law 102–486, 106 Stat. 2776 (42 U.S.C. 2296a *et seq.*).

Issued in Washington DC on May 12, 2016.

Theresa Kliczewski,

Office of Disposition Planning & Policy, Office of Environmental Management.

[FR Doc. 2016–11700 Filed 5–17–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–119–000.

Applicants: Beech Ridge Energy LLC, Beech Ridge Energy II LLC, Beech Ridge Energy Storage LLC, Bethel Wind Farm LLC, Bishop Hill Energy III LLC, Bishop Hill Interconnection LLC, Buckeye Wind Energy LLC, Forward Energy LLC, Grand Ridge Energy LLC, Grand Ridge Energy II LLC, Grand Ridge Energy III LLC, Grand Ridge Energy IV LLC, Grand Ridge Energy V LLC, Grand Ridge Energy Storage LLC, Gratiot County Wind LLC, Gratiot County Wind II LLC, Invenergy TN LLC, Judith Gap Energy LLC, Peak View Wind Energy LLC, Prairie Breeze Wind Energy II LLC, Prairie Breeze Wind Energy III LLC, Sheldon Energy LLC, Spring Canyon Energy LLC, Stony Creek Energy LLC, Vantage Wind Energy LLC, Willow Creek Energy LLC, Wolverine Creek Energy LLC, Wolverine Creek Goshen Interconnection LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act and Request for Waivers and Expedited Action of Beech Ridge Energy LLC, et al.

Filed Date: 5/12/16.

Accession Number: 20160512–5193.

Comments Due: 5 p.m. ET 6/2/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–236–002.

Applicants: Public Service Company of Colorado.

Description: Compliance filing: 2016–5–12 Att SPS/PSCo ADIT Filing to be effective 1/1/2016.

Filed Date: 5/12/16.

Accession Number: 20160512–5197.

Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–239–002.

Applicants: Public Service Company of Colorado.

Description: Compliance filing: 20160512_ER16–239 ADIT Compliance Filing to be effective 1/1/2016.

Filed Date: 5/12/16.

Accession Number: 20160512–5207.

Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–551–002

Applicants: ISO New England Inc.

Description: Compliance filing: 30-Day Compliance Filing to Establish Materiality Threshold for Retirement Bids to be effective 3/1/2016.

Filed Date: 5/12/16.

Accession Number: 20160512–5191.

Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–736–002.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Response to Deficiency Notice issued 4/12/2016 in Docket No. ER16–736–001 to be effective 4/14/2016.

Filed Date: 5/12/16.

Accession Number: 20160512–5212.

Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–1226–000.

Applicants: New Covert Generating Company, LLC.

Description: Supplement to March 18, 2016 New Covert Generating Company, LLC tariff filing.

Filed Date: 5/12/16.

Accession Number: 20160512–5215.

Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–1682–000.

Applicants: Public Service Company of Colorado.

Description: Compliance filing: 20160512 ER16–239 ADIT Filing to be effective 4/16/2016.

Filed Date: 5/12/16.

Accession Number: 20160512–5176.

Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–1683–000.

Applicants: Wolverine Power Supply Cooperative, Inc.

Description: Section 205(d) Rate Filing: Van Tyle Station Transmission Facilities Agreement to be effective 5/5/2016.

Filed Date: 5/12/16.

Accession Number: 20160512–5182.

Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–1684–000.

Applicants: Idaho Power Company.

Description: Section 205(d) Rate Filing: Concurrence—Construction Agreement w/PAC Goshen-Jefferson 161 kV Line Rebuild to be effective 7/11/2016.

Filed Date: 5/12/16.

Accession Number: 20160512–5184.

Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–1685–000.

Applicants: Escalante Solar II, LLC.

Description: Compliance filing: Compliance Filing—Amendment to MBR Tariff Limits and Exemptions to be effective 7/11/2016.

Filed Date: 5/12/16.

Accession Number: 20160512–5192.

Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–1686–000.

Applicants: Public Service Company of Colorado.

Description: Compliance filing: Attachment O–PSCo_SPS ADIT Compliance filing to be effective 4/16/2016.

Filed Date: 5/12/16.

Accession Number: 20160512–5202.

Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–1687–000.

Applicants: PJM Interconnection, L.L.C.

Description: Section 205(d) Rate Filing: Original WMPA SA No. 4458, Queue No. AA1–110 to be effective 4/27/2016.

Filed Date: 5/12/16.

Accession Number: 20160512–5219.

Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–1688–000.

Applicants: Southern California Edison Company.

Description: Section 205(d) Rate Filing: Three Amended SGIA's & DSA's w/Golden Springs Development Company to be effective 1/1/2016.

Filed Date: 5/12/16.

Accession Number: 20160512–5225.

Comments Due: 5 p.m. ET 6/2/16.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF16–784–000.

Applicants: Energy Partners II, LLC.

Description: Form 556 of Energy Partners II, LLC.

Filed Date: 5/2/16.

Accession Number: 20160502–5397.

Comments Due: None Applicable.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 12, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–11711 Filed 5–17–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–118–000.

Applicants: Castleton Energy Services, LLC, Castleton Power, LLC, Fortistar Castleton LLC.

Description: Application of Castleton Energy Services, LLC, et al. for Authorization Under Section 203 of the Federal Power Act and Requests for Waivers, Confidential Treatment and Expedited Action.

Filed Date: 5/10/16.

Accession Number: 20160510–5185.

Comments Due: 5 p.m. ET 5/31/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–1277–001.

Applicants: White Pine Solar, LLC.

Description: Tariff Amendment: White Pine Solar, LLC's Amendment to Application for Market-Based Rates to be effective 5/24/2016.

Filed Date: 5/4/16.

Accession Number: 20160504–5225.

Comments Due: 5 p.m. ET 5/25/16.

Docket Numbers: ER16–1293–001.

Applicants: White Oak Solar, LLC.

Description: Tariff Amendment: White Oak Solar, LLC's Amendment to Application for Market-Based Rates to be effective 5/29/2016.

Filed Date: 5/4/16.

Accession Number: 20160504–5226.

Comments Due: 5 p.m. ET 5/25/16.

Docket Numbers: ER16–1354–001.

Applicants: Live Oak Solar, LLC.

Description: Tariff Amendment: Live Oak Solar, LLC's Amendment to the Application for Market-Based Rates to be effective 9/1/2016.

Filed Date: 5/4/16.

Accession Number: 20160504–5224.

Comments Due: 5 p.m. ET 5/25/16.

Docket Numbers: ER16–1662–000.

Applicants: 4C Acquisition, LLC.

Description: Application of 4C Acquisition, LLC for Waiver of OATT, OASIS and Standards of Conduct Requirements.

Filed Date: 5/6/16.

Accession Number: 20160506–5280.

Comments Due: 5 p.m. ET 5/27/16.

Docket Numbers: ER16–1663–000.

Applicants: Southern California Edison Company.

Description: Section 205(d) Rate Filing: Service Agreement with Rosamond Energy, LLC to be effective 5/5/2016.

Filed Date: 5/11/16.

Accession Number: 20160511–5099.

Comments Due: 5 p.m. ET 6/1/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 11, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–11708 Filed 5–17–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–1672–000]

Chaves County Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Chaves County Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is June 1, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 12, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–11712 Filed 5–17–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–1825–005.
Applicants: California Independent System Operator Corporation.
Description: Compliance filing: 2016–05–11 Filing in Compliance with April 29 Order Delaying RSI Effective Date to be effective 6/1/2016.
Filed Date: 5/11/16.
Accession Number: 20160511–5231.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–897–003.
Applicants: California Independent System Operator Corporation.
Description: Compliance filing: 2016–05–11 Filing in Compliance with April 29 Order Delaying CPM Effective Date to be effective 4/25/2016.
Filed Date: 5/11/16.
Accession Number: 20160511–5239.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–943–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Tariff Amendment: 2016–05–11_SA 2896 Deficiency Response METC–WPSC GIA (J392) to be effective 2/17/2016.
Filed Date: 5/11/16.
Accession Number: 20160511–5235.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–1353–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Tariff Amendment: 2016–05–11_SA 2896 Deficiency Response METC–WPSC 1st Rev. GIA (J392) to be effective 4/7/2016.
Filed Date: 5/11/16.
Accession Number: 20160511–5237.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–1664–000.
Applicants: New York Independent System Operator, Inc.
Description: Tariff Cancellation: Notice of cancellation SA 1698 among NYISO, NMPC and Roaring Brook to be effective 7/26/2016.
Filed Date: 5/11/16.
Accession Number: 20160511–5122.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–1665–000.
Applicants: Glacial Energy of California, Inc.
Description: Notice of cancellation of market based tariff of Glacial Energy of California, Inc.
Filed Date: 5/11/16.
Accession Number: 20160511–5188.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–1666–000.
Applicants: Glacial Energy of New York.
Description: Notice of cancellation of market based tariff of Glacial Energy of New York.
Filed Date: 5/11/16.
Accession Number: 20160511–5213.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–1667–000.
Applicants: PJM Interconnection, L.L.C.
Description: Section 205(d) Rate Filing: Amendment to WMPA SA No. 4066, Queue No. Y1–079 per Assignment to Allegheny to be effective 7/2/2015.
Filed Date: 5/11/16.
Accession Number: 20160511–5214.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–1669–000.
Applicants: NorthWestern Corporation.
Description: Section 205(d) Rate Filing: SA 31 15th Rev—NITSA with Phillips 66 Company to be effective 6/1/2016.
Filed Date: 5/11/16.
Accession Number: 20160511–5232.
Comments Due: 5 p.m. ET 6/1/16.

Take notice that the Commission received the following PURPA 210(m)(3) filings:

Docket Numbers: QM16–4–000.
Applicants: Hoosier Energy Rural Electric Coop. Inc.
Description: Application of Hoosier Energy Rural Electric Cooperative, Inc. to Terminate QF Mandatory Purchase Obligation.
Filed Date: 5/11/16.
Accession Number: 20160511–5243.
Comments Due: 5 p.m. ET 6/8/16.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RD16–5–000.
Applicants: North American Electric Reliability Corporation.
Description: Petition of the North American Electric Reliability Corporation for Approval of the Revised Definition of Special Protection System.
Filed Date: 5/11/16.
Accession Number: 20160511–5173.
Comments Due: 5 p.m. ET 6/10/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 11, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–11709 Filed 5–17–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1852–013; ER10–1971–026; ER11–4462–017.
Applicants: Florida Power & Light Company, NextEra Energy Power Marketing, LLC, NEPM II, LLC.
Description: Notice of Change in Status Update of the NextEra Companies, et al.
Filed Date: 5/11/16.
Accession Number: 20160511–5305.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–474–002.
Applicants: Central Antelope Dry Ranch C LLC.
Description: Compliance filing: Central Antelope Dry Ranch C LLC MBR Tariff to be effective 2/1/2016.
Filed Date: 5/12/16.
Accession Number: 20160512–5002.
Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–1670–000.
Applicants: PacifiCorp.
Description: Section 205(d) Rate Filing: Idaho Power Construct Agmt Goshen-Jefferson Line Rebuild to be effective 7/11/2016.
Filed Date: 5/11/16.
Accession Number: 20160511–5246.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–1671–000.
Applicants: Florida Power & Light Company.
Description: Section 205(d) Rate Filing: FPL's Open Access Transmission Tariff Clean-Up to be effective 5/12/2016.
Filed Date: 5/11/16.
Accession Number: 20160511–5262.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–1672–000.
Applicants: Chaves County Solar, LLC.
Description: Baseline eTariff Filing: Chaves County Solar, LLC Application for Market-Based Rates to be effective 9/1/2016.
Filed Date: 5/11/16.
Accession Number: 20160511–5263.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–1673–000.
Applicants: Glacial Energy of New England, Inc.
Description: Notice of cancellation of market based tariff of Glacial Energy of New England, Inc.
Filed Date: 5/11/16.
Accession Number: 20160511–5264.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–1674–000.
Applicants: Glacial Energy of New Jersey, Inc.
Description: Notice of cancellation of market based tariff of Glacial Energy of New Jersey, Inc.
Filed Date: 5/11/16.
Accession Number: 20160511–5265.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–1675–000.
Applicants: Glacial Energy of Illinois, Inc.
Description: Notice of cancellation of market based tariff of Glacial Energy of Illinois, Inc.
Filed Date: 5/11/16.
Accession Number: 20160511–5266.
Comments Due: 5 p.m. ET 6/1/16.

Docket Numbers: ER16–1676–000.
Applicants: Southwest Power Pool, Inc.
Description: Section 205(d) Rate Filing: 3180 Basin Electric and Montana-Dakota Utilities Att AO to be effective 6/1/2016.
Filed Date: 5/12/16.
Accession Number: 20160512–5044.
Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–1677–000.
Applicants: Enterprise Solar, LLC.
Description: Compliance filing: Compliance Filing—Amendment to MBR Limitations and Exemptions to be effective 7/11/2016.
Filed Date: 5/12/16.
Accession Number: 20160512–5097.
Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–1678–000.
Applicants: PJM Interconnection, L.L.C.
Description: Section 205(d) Rate Filing: Service Agreement No. 4447, Queue Position AB1–025 to be effective 4/12/2016.
Filed Date: 5/12/16.
Accession Number: 20160512–5107.
Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–1679–000.
Applicants: PJM Interconnection, L.L.C.
Description: Section 205(d) Rate Filing: Service Agreement Nos. 4448, 4449, 4450, Queue Nos. AB1–021, AB1–063, AB1–139 to be effective 4/12/2016.
Filed Date: 5/12/16.
Accession Number: 20160512–5109.
Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–1680–000.
Applicants: Escalante Solar I, LLC.
Description: Compliance filing: Compliance Filing—Amendment to MBR Tariff Limits. and Exemptions to be effective 7/11/2016.
Filed Date: 5/12/16.
Accession Number: 20160512–5140.
Comments Due: 5 p.m. ET 6/2/16.

Docket Numbers: ER16–1681–000.
Applicants: PacifiCorp.
Description: Tariff Cancellation: Termination of BPA Agmt for Pilot Butte Sub Mtring & Trnsfr CEC to BPA BAA to be effective 7/24/2016.
Filed Date: 5/12/16.
Accession Number: 20160512–5164.
Comments Due: 5 p.m. ET 6/2/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 12, 2016.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2016–11710 Filed 5–17–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2013–0290 and EPA–HQ–OAR–2013–0291; FRL–9946–63–OAR]

NESHAP for Brick and Structural Clay Products Manufacturing; and NESHAP for Clay Ceramics Manufacturing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of action denying in part and granting in part petitions for reconsideration.

SUMMARY: This action provides notice that the U.S. Environmental Protection Agency (EPA) Administrator, Gina McCarthy, denied in part and granted in part petitions for reconsideration of the final National Emission Standards for Hazardous Air Pollutants (NESHAP) for Brick and Structural Clay Products (BSCP) Manufacturing and the final NESHAP for Clay Ceramics Manufacturing published in the **Federal Register** on October 26, 2015.

DATES: This action is effective on May 18, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Sharon Nizich, Minerals and

Manufacturing Group, Sector Policies and Programs Division (D243–04), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2825; email address: *nizich.sharon@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. How can I get copies of this document and other related information?

This **Federal Register** notice, the petitions for reconsideration, and the letters and accompanying enclosures addressing the petitions for reconsideration are available in the dockets the EPA established under Docket ID No. EPA–HQ–OAR–2013–0291 for BSCP Manufacturing and Docket ID No. EPA–HQ–OAR–2013–0290 for Clay Ceramics Manufacturing.

All documents in the dockets are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the EPA Docket Center (EPA/DC), EPA WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the Air Docket is (202) 566–1742. This **Federal Register** document, the petitions for reconsideration, and the letters with the accompanying enclosure addressing the petitions can also be found on the EPA's Web site at *http://www.epa.gov/ttn/oarpg.*

II. Judicial Review

Section 307(b)(1) of the Clean Air Act (CAA) indicates which Federal Courts of Appeals have venue for petitions for review of final EPA actions. This section provides, in part, that the petitions for review must be filed in the Court of Appeals for the District of Columbia Circuit if: (i) The agency action consists of "nationally applicable regulations promulgated, or final action taken, by the Administrator," or (ii) such actions are locally or regionally applicable, if "such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination."

The EPA has determined that its denial of the petitions for reconsideration is nationally applicable for purposes of CAA section 307(b)(1) because the actions directly affect the BSCP Manufacturing NESHAP and Clay Ceramics Manufacturing NESHAP, which are nationally applicable regulations. Thus, any petitions for review of the letters and enclosures denying the petitions for reconsideration described in this document must be filed in the United States Court of Appeals for the District of Columbia Circuit by July 18, 2016.

To the extent that EPA is granting the petitions for reconsideration with respect to certain issues, such grant is not final agency action, but only begins an agency process to consider whether the rule should be revised. If EPA in the future takes final agency action to revise the rule, notice of such action will be published in the **Federal Register** and judicial review will be available at that time.

III. Description of Action

The initial NESHAP for BSCP Manufacturing and initial NESHAP for Clay Ceramics Manufacturing were published in the **Federal Register** on May 16, 2003 (68 FR 26690), and codified at 40 CFR part 63, subparts JJJJJ and KKKKK, respectively, pursuant to section 112 of the CAA. Those standards were challenged and subsequently vacated by the United States Court of Appeals for the District of Columbia Circuit in 2007. See *Sierra Club* v. *EPA,* 479 F.3d 875, 876 (D.C. Cir. 2007). Following the 2007 vacatur of the 2003 rule, the EPA collected additional data and information to support new standards for the BSCP and clay ceramics industries. This information is contained in the dockets for both rules, which are available at *http://www.regulations.gov.* On December 18, 2014, the EPA proposed new NESHAP for BSCP Manufacturing and for Clay Ceramics Manufacturing (79 FR 75622). The EPA received additional data and comments during the public comment period. These data and comments were considered and analyzed and, where appropriate, revisions to the two NESHAP were made. The NESHAP for BSCP Manufacturing and NESHAP for Clay Ceramics Manufacturing were finalized on October 26, 2015 (80 FR 65470).

On December 23, 2015, Kohler Company submitted a petition for reconsideration of the final rule for Clay Ceramics Manufacturing (80 FR 65470). In support of its petition, Kohler Company claimed that: (1) The final rule introduced new stack temperature monitoring requirements for demonstrating compliance with the dioxin/furan emission limits without an opportunity for comment by the petitioner; (2) the EPA failed to adequately respond to the petitioner's public comments regarding visible emissions monitoring in the response to comments and final rule; (3) the EPA should reconsider its exclusion of emissions averaging from the final rule as a compliance option for clay ceramics manufacturing; (4) the EPA should reconsider its improper use of scrubber emissions data from the petitioner's South Carolina Kiln 10 for determining the maximum achievable control technology (MACT) floor; (5) the EPA should reconsider the frequency of onerous and unnecessary visual inspection requirements for system ductwork and control device equipment for water curtain spray booths; and (6) the EPA should clarify the testing threshold for cooling stacks to be tested to limit it to those stacks with an oxygen content at or below 20.4 percent.

Also on December 23, 2015, the Brick Industry Association (BIA) submitted a petition for reconsideration of the final rule for BSCP Manufacturing (80 FR 65470). In support of its petition, the BIA claimed that: (1) The EPA failed to give notice that it would change its method for calculating the existing source MACT floor for emissions of non-mercury (Hg) hazardous air pollutant (HAP) metals; (2) the EPA incorrectly used tests conducted below capacity in its revised MACT floor approach; (3) the EPA failed to give notice that it would include a variability calculation in its determination of the MACT floor for Hg or how it would make this variability calculation; (4) it was impracticable for the petitioner to request a variability factor for non-Hg metal emission limits for the final rule; and (5) the EPA failed to give notice that it would include opacity as a compliance method for the non-Hg HAP metals standard.

On December 24, 2015, the Tile Council of North America, Inc. (TCNA) and its members submitted a petition for reconsideration of the final rule for Clay Ceramics Manufacturing (80 FR 65470). In support of its petition, the TCNA claimed that: (1) In promulgating the final rule, the EPA relied on legal positions/rationales for regulating ceramic tile that were advanced for the first time in the preamble to the final rule; (2) for the final rule, the EPA introduced for the first time the technical rationale that Method 23 field blank spike recoveries self-validate the dioxin/furan emissions data used to set dioxin/furan standards; and (3) the EPA failed to respond to public comments regarding the cost of the final rule to those sources that the EPA postulates might at some time in the future become subject to the rule.

Section 307(d)(7)(B) of the CAA sets forth the criteria for reconsideration. That section states that "(o)nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. If the person raising an objection can demonstrate to the Administrator that it was impractical to raise such objection within such time or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed."

The EPA has carefully considered the petitions and supporting information. In separate letters to the petitioners, the EPA Administrator, Gina McCarthy, denied in part and granted in part the Kohler Company petition, denied the BIA and TCNA petitions, and explained the reasons for the denials. These letters and the accompanying enclosures are available in the dockets for this action.

IV. Conclusion

For the reasons discussed in the letters and accompanying enclosure to the petitioners, the petitions to reconsider the final NESHAP for BSCP Manufacturing and final NESHAP for Clay Ceramics Manufacturing are denied in part and granted in part.

Dated: May 12, 2016.

Gina McCarthy,

Administrator.

[FR Doc. 2016–11749 Filed 5–17–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0742]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before July 18, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0742.

Title: Sections 52.21 through 52.36, Telephone Number Portability, 47 CFR part 52, subpart (C) and CC Docket No. 95–116.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 3,631 respondents; 10,002,005 responses.

Estimated Time per Response: 4 minutes–10 hours.

Frequency of Response: On occasion and one time reporting requirements, recordkeeping requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 152, 154(i), 201–205, 215, 251(b)(2), 251(e)(2) and 332 of the Communications Act of 1934, as amended.

Total Annual Burden: 673,460 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact.

Nature and Extent of Confidentiality: The Commission is not requesting respondents to submit confidential information to the Commission. If the respondents wish confidential treatment of their information, they may request confidential treatment under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: Section 251(b)(2) of the Communications Act of 1934, as amended, requires LECs to "provide, to the extent technically feasible, number portability in accordance with requirements prescribed by the Commission." Through the LNP process, consumers have the ability to retain their phone number when switching telecommunications service providers, enabling them to choose a provider that best suits their needs and enhancing competition. In the *Porting Interval Order and Further Notice*, the Commission mandated a one business day porting interval for simple wireline-to-wireline and intermodal port requests. The information collected in the standard local service request data fields is necessary to complete simple wireline-to-wireline and intermodal ports within the one business day porting interval mandated by the Commission and will be used to comply with section 251 of the Telecommunications Act of 1996.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2016–11691 Filed 5–17–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0466]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before July 18, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0466.

Title: Sections 73.1201, 74.783 and 74.1283, Station Identification.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not for-profit institutions; State, local or Tribal Government.

Number of Respondents and Responses: 24,083 respondents; 24,083 responses.

Estimated Time per Response: 0.166–1 hour.

Frequency of Response: On occasion reporting requirement; Recordkeeping requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or maintain benefits. The statutory authority for this collection of information is contained in 47 U.S.C. 151, 152, 154(i), 303, 307 and 308.

Total Annual Burden: 23,249 hours.

Total Annual Cost: None.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: 47 CFR 73.1201(a) requires television broadcast licensees to make broadcast station identification announcements at the beginning and ending of each time of operation, and hourly, as close to the hour as feasible, at a natural break in program offerings. Television and Class A television broadcast stations may make these announcements visually or aurally.

47 CFR 74.783(b) requires licensees of television translators whose station identification is made by the television station whose signals are being rebroadcast by the translator, must secure agreement with this television station licensee to keep in its file, and available to FCC personnel, the translator's call letters and location, giving the name, address and telephone number of the licensee or his service representative to be contacted in the event of malfunction of the translator. It shall be the responsibility of the translator licensee to furnish current information to the television station licensee for this purpose.

47 CFR 73.1201(b)(1) requires that the official station identification consist of the station's call letters immediately followed by the community or communities specified in its license as the station's location. The name of the licensee, the station's frequency, the station's channel number, as stated on the station's license, and/or the station's network affiliation may be inserted between the call letters and station location. Digital Television (DTV) stations, or DAB Stations, choosing to include the station's channel number in the station identification must use the station's major channel number and may distinguish multicast program streams. For example, a DTV station with major channel number 26 may use 26.1 to identify a High Definition Television (HDTV) program service and 26.2 to identify a Standard Definition Television (SDTV) program service. A radio station operating in DAB hybrid mode or extended hybrid mode shall identify its digital signal, including any free multicast audio programming streams, in a manner that appropriately alerts its audience to the fact that it is listening to a digital audio broadcast. No other insertion between the station's call letters and the community or communities specified in its license is permissible. A station may include in its official station identification the name of any additional community or communities, but the community to which the station is licensed must be named first.

47 CFR 74.783(e) permits low power TV permittees or licensees to request to be assigned four-letter call signs in lieu of the five-character alpha-numeric call signs.

47 CFR 74.1283(c)(1) requires a FM translator station licensee whose identification is made by the primary station must arrange for the primary station licensee to furnish the translator's call letters and location (name, address, and telephone number of the licensee or service representative) to the FCC. The licensee must keep this information in the primary station's files.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2016–11690 Filed 5–17–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to all Interested Parties of the Termination of the Receivership of 10370, First Commercial Bank of Tampa, Tampa, Florida

Notice is hereby given that the Federal Deposit Insurance Corporation ("FDIC") as Receiver for First Commercial Bank of Tampa, Tampa, Florida ("the Receiver") intends to terminate its receivership for said institution. The FDIC was appointed receiver of First Commercial Bank of Tampa on June 17, 2011. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors. Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: May 13, 2016.

Federal Deposit Insurance Corporation

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–11699 Filed 5–17–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 011426–060.

Title: West Coast of South America Discussion Agreement.

Parties: CMA CGM S.A.; Hamburg-Süd; Hapag-Lloyd AG; Mediterranean Shipping Company, SA; Seaboard Marine Ltd.; and Trinity Shipping Line, S.A.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Conner; 1200 Nineteenth Street NW.; Washington, DC 20036.

Synopsis: The amendment deletes King Ocean Services Limited, Inc. as a party to the agreement and reflects the resignation of Trinity Shipping Line, S.A., effective June 8, 2016.

Agreement No.: 012233–004.

Title: UASC/CMA CGM/PIL Vessel Sharing Agreement—Asia and US West Coast Services.

Parties: United Arab Shipping Company (S.A.G.); CMA CGM S.A.; and Pacific International Lines (Pte) Ltd.

Filing Party: Joshua P. Stein; Cozen O'Connor; 1200 Nineteenth Street NW., Washington DC, 20036.

Synopsis: The amendment changes the name of the agreement to the UASC/CMA CGM/PIL Vessel Sharing Agreement—Asia and US West Coast Services and deletes COSCON, CSCL and YMUK as parties to the agreement. It also deletes the structural slot exchange component of the agreement.

Agreement No.: 012336–001.

Title: ZIM/OOCL Space Charter Agreement.

Parties: Zim Integrated Shipping Services Co., Ltd. and Orient Overseas Container Line Limited.

Filing Party: Mark E. Newcomb; ZIM American Integrated Shipping Services, Co. LLC; 5801 Lake Wright Dr.; Norfolk, VA 23508.

Synopsis: The amendment authorizes Zim to charter space to OOCL in the trade between the Atlantic Coast of the U.S. and Malaysia.

Agreement No.: 012410.

Title: WWL/Hyundai Glovis Space Charter Agreement.

Parties: Wallenius Wilhelmsen Logistics AS and Hyundai Glovis Co. Ltd.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor LLP; 1200 Nineteenth St. NW.; Washington, DC 200036.

Synopsis: The Agreement authorizes the parties to charter space to/from one another on an "as needed/as available" basis from Korea on the one hand, to ports on the Atlantic Coast of the U.S. and Puerto Rico on the other hand.

By Order of the Federal Maritime Commission.

Dated: May 13, 2016.

Karen V. Gregory,

Secretary.

[FR Doc. 2016–11748 Filed 5–17–16; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL MARITIME COMMISSION

[Docket No. 16–12]

Pro Transport, Inc., Pro Transport Jacksonville, Inc., Pro Transport Savannah, Inc., and Pro Transport Charleston, Inc. V. Seaboard Marine of Florida, Inc. and Seaboard Marine Ltd., Inc.; Notice of Filing of Complaint and Assignment

Notice is given that a Complaint has been filed with the Federal Maritime Commission (Commission) by Pro Transport, Inc., Pro Transport Jacksonville, Inc., Pro Transport Savannah, Inc. and Pro Transport Charleston, Inc., hereinafter "Complainants," against Seaboard Marine of Florida, Inc., and Seaboard Marine Ltd., Inc., hereinafter "Respondents." Complainants state that they are "motor carriers that provide transportation and transportation services, primarily to and from commercial ports along the southeastern seaboard of the United States." Complainants allege that Respondents "acted as an ocean common carrier, a marine terminal operator, and/or as an agent for an ocean common carrier."

Complainants allege that Respondents have violated Sections 10(b)(10), 10(d)(3), and 10(d)(4) of the Shipping Act of 1984, 46 U.S.C. 41104(10) and 46 U.S.C. 41106(2–3), because they refused to pay Complainants for services, terminated their relationship, and refuse to cooperate on outstanding insurance claims.

Complainants request the following relief: That Seaboard answer the charges in the complaint; be ordered to cease and desist from the aforesaid violations of the Shipping Act; establish and put in force such practices as the Commission determines to be lawful and reasonable; pay reparations to Complainants for alleged unlawful conduct in an amount the Commission may determine to be proper, with interest and attorney's fees and costs; and that the Commission issue such other and further order(s) as the Commission determines to be proper.

The full text of the complaint can be found in the Commission's Electronic Reading Room at *www.fmc.gov/16-12.*

This proceeding has been assigned to the Office of Administrative Law Judges. The initial decision of the presiding officer in this proceeding shall be issued by May 12, 2017 and the final decision of the Commission shall be issued by November 27, 2017.

Karen V. Gregory,

Secretary.

[FR Doc. 2016–11671 Filed 5–17–16; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 10, 2016.

A. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Henderson Citizens Bancshares, Inc.*, Henderson, Texas; to acquire by merger 100 percent of Kilgore National Financial Corporation, and indirectly, Kilgore National Bank, both of Kilgore, Texas.

Board of Governors of the Federal Reserve System, May 12, 2016.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2016–11634 Filed 5–17–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act; Notice of Meeting

Agenda

Federal Retirement Thrift Investment, Joint Board Member/ETAC Meeting, May 23, 2016, 8:30 a.m. (In-Person), 77 K Street NE., Training Room, Washington, DC 20002.

Open Session

1. Approval of the Minutes of the April 25, 2016 Board Member Meeting
2. Approval of the Minutes of the October 26, 2015 ETAC Meeting
3. Monthly Reports
   (a) Participant Activity Report
   (b) Investment Performance Report
   (c) Legislative Report
4. Quarterly Reports
   (d) Metrics
   (e) Project Activity
5. ExPRESS Brief
6. Blended Retirement
7. Office of Communication and Education Report

Closed Session

8. Security
9. Personnel

Adjourn

CONTACT PERSON FOR MORE INFORMATION: Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

Dated: May 13, 2016.

Megan Grumbine,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2016–11752 Filed 5–16–16; 11:15 am]

BILLING CODE 6760–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0091; Docket 2016–0053; Sequence 26]

Information Collection; Anti-Kickback Procedures

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension of an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning anti-kickback procedures.

DATES: Submit comments on or before July 18, 2016.

ADDRESSES: Submit comments identified by Information Collection 9000–0091, Anti-Kickback Procedures, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 9000–0091, Anti-Kickback Procedures". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000–0091, Anti-Kickback Procedures" on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405–0001. ATTN: Ms. Flowers/IC 9000–0091, Anti-Kickback Procedures.

Instructions: Please submit comments only and cite Information Collection 9000–0091, Anti-Kickback Procedures, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov*, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov*, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Cecelia L. Davis, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA, 202–219–0202 or email *cecelia.davis@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Federal Acquisition Regulation (FAR) 52.203–7, Anti-Kickback Procedures, requires that all contractors have in place and follow reasonable procedures designed to prevent and detect in its own operations and direct business relationships, violations of 41 U.S.C. chapter 87, Kickbacks. Whenever prime contractors or subcontractors have reasonable grounds to believe that a violation of the statute may have occurred, they are required to report the possible violation in writing to the contracting agency inspector general, the head of the contracting agency if an agency does not have an inspector general, or the Department of Justice. The information is used to determine if any violations of the statute have occurred.

There is no Governmentwide data collection process or system which identifies the number of alleged violations of 41 U.S.C. chapter 87, Kickbacks that are reported annually to agency inspectors general, the heads of the contracting agency if an agency does not have an inspector general, or the Department of Justice.

B. Annual Reporting Burden

Respondents: 100.
Responses per Respondent: 1.
Annual Responses: 100.
Hours per Response: 20.
Total Burden Hours: 2,000.
Affected Public: Businesses or other for-profit and not for profit institutions.
Frequency: On occasion.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street Street NW., Washington, DC 20405, telephone 202–501–4755.

Please cite OMB Control No. 9000–0091, Anti-Kickback Procedures, in all correspondence.

Dated: May 12, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–11686 Filed 5–17–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0078; Docket 2016–0053; Sequence 14]

Submission for OMB Review; Make-or-Buy Program

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension to an information collection requirement for an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning the Make-or-Buy Program.

DATES: Submit comments on or before June 17, 2016.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

- *Regulations.gov: http:// www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 9000–0078, Make-or-Buy Program". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000–0078, Make-or-Buy Program" on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0078, Make-or-Buy Program.

Instructions: Please submit comments only and cite Information Collection 9000–0078, Make-or-Buy Program, in all correspondence related to this collection. Comments received generally will be posted without change to *http:// www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Edward Loeb, Procurement Analyst, Office of Acquisition Policy, GSA, 202–501–0650 or via email at *edward.loeb@ gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Price, performance, and/or implementation of socio-economic policies may be affected by make-or-buy decisions under certain Government prime contracts. Accordingly, FAR 15.407–2, Make-or-Buy Programs:

(i) Sets forth circumstances under which a Government contractor must submit for approval by the contracting officer a make-or-buy program, *i.e.,* a written plan identifying major items to be produced or work efforts to be performed in the prime contractor's facilities and those to be subcontracted;

(ii) Provides guidance to contracting officers concerning the review and approval of the make-or-buy programs; and

(iii) Prescribes the contract clause at FAR 52.215–9, Changes or Additions to Make-or-Buy Programs, which specifies the circumstances under which the contractor is required to submit for the contracting officer's advance approval a notification and justification of any proposed change in the approved make-or-buy program.

The information is used to assure the lowest overall cost to the Government for required supplies and services. A notice was published in the **Federal Register** at 81 FR 12493 on March 9, 2016. No comments were received.

B. Annual Reporting Burden

Respondents: 150.

Responses per Respondent: 3.

Total Responses: 450.

Hours per Response: 8.

Total Burden Hours: 3,600.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulation (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0078, Make-or-Buy Program, in all correspondence.

Dated: May 12, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–11685 Filed 5–17–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0102; Docket 2016–0053; Sequence 20]

Submission for OMB Review; Prompt Payment

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension to a previously approved information collection requirement concerning prompt payment.

DATES: Submit comments on or before June 17, 2016.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 9000–0102, Prompt Payment". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000–0102, Prompt Payment" on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0102, Prompt Payment.

Instructions: Please submit comments only and cite Information Collection 9000–0102, Prompt Payment, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Kathlyn Hopkins, Procurement Analyst, Office of Acquisition Policy, GSA 202–969–7226 or email *kathlyn.hopkins@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Part 32 of the FAR and the clause at FAR 52.232–5, Payments Under Fixed-Price Construction Contracts, require that contractors under fixed-price construction contracts certify, for every progress payment request, that payments to subcontractors/suppliers have been made from previous payments received under the contract and timely payments will be made from the proceeds of the payment covered by the certification, and that this payment request does not include any amount which the contractor intends to withhold from a subcontractor/supplier. Part 32 of the FAR and the clause at 52.232–27, Prompt Payment for Construction Contracts, further require that contractors on construction contracts:

(a) Notify subcontractors/suppliers of any amounts to be withheld and furnish a copy of the notification to the contracting officer;

(b) Pay interest to subcontractors/suppliers if payment is not made by 7 days after receipt of payment from the Government, or within 7 days after correction of previously identified deficiencies;

(c) Pay interest to the Government if amounts are withheld from subcontractors/suppliers after the Government has paid the contractor the amounts subsequently withheld, or if the Government has inadvertently paid the contractor for nonconforming performance; and

(d) Include a payment clause in each subcontract which obligates the contractor to pay the subcontractor for satisfactory performance under its subcontract no later than seven days after such amounts are paid to the contractor, include an interest penalty clause which obligates the contractor to pay the subcontractor an interest penalty if payments are not made in a timely manner, and include a clause requiring each subcontractor to include these clauses in each of its subcontractors and to require each of its subcontractors to include similar clauses in their subcontracts.

These requirements are imposed by Public Law 100–496, the Prompt Payment Act Amendments of 1988.

Contracting officers will be notified if the contractor withholds amounts from subcontractors/suppliers after the Government has already paid the contractor the amounts withheld. The contracting officer must then charge the contractor interest on the amounts withheld from subcontractors/suppliers. Federal agencies could not comply with the requirements of the law if this information were not collected. A notice was published in the **Federal Register** at 81 FR 11795 on March 7, 2016. No comments were received.

B. Annual Reporting Burden

Respondents: 807.

Responses per Respondent: 11.

Total Responses: 8,877.

Hours per Response: .25.

Total Burden Hours: 2,219.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755.

Please cite OMB Control No. 9000–0102, Prompt Payment, in all correspondence.

Dated: May 12, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–11687 Filed 5–17–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Interstate Administrative Subpoena and Notice of Interstate Lien.

OMB No.: 0970–0152.

Description: Section 452(a)(11) of the Social Security Act requires the Secretary of the Department of Health and Human Services to promulgate a form for administrative subpoenas and imposition of liens used by State child support enforcement (title IV–D) agencies. The Interstate Administrative Subpoena is used to collect information for the establishment, modification and enforcement of child support orders in interstate cases. Section 454(9)(E) of the Social Security Act requires each State to cooperate with any other State in using the federal form for issuance of administrative subpoenas and imposition of liens in interstate child support cases. Tribal IV–D agencies are not required to use this form but may choose to do so. OMB approval of these forms are expiring in December, 2016 and the Administration for Children and Families is requesting an extension of this form.

Respondents: State, local or Tribal agencies administering a child support enforcement program under title IV–D of the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Administrative Subpoena	31,344	1	0.50	15,672
Notice of Lien	1,916,891	1	0.25	479,223

Estimated Total Annual Burden Hours: 494,895.

In compliance with the requirements of section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–11633 Filed 5–17–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of the Assistant Secretary; Statement of Delegation of Authority

Notice is hereby given that on January 27, 2016, the Assistant Secretary for Children and Families re-delegated certain responsibilities under the Trafficking Victims Protection Act of 2000 (TVPA), as amended, to the Director of the Office on Trafficking in Persons (OTIP), an office within the Immediate Office of the Assistant Secretary. In addition, the Assistant Secretary delegated to OTIP other authorities under sections 107(b) and 107(f) of the TVPA. By virtue of these re-delegations, certain previously delegated authorities to the Office of Refugee Resettlement (ORR) were rescinded.

By virtue of the authority vested in the Assistant Secretary by the Secretary of Health and Human Services on April 30, 2004, I rescinded the following delegation to the Director of ORR made on January 11, 2008 (73 FR 5198) and re-delegated the responsibilities to the Director of OTIP, with the authority to re-delegate:

Authority to conduct public awareness and information activities under section 106(b) of the TVPA (22 U.S.C. 7104(b)).

By virtue of the authority vested in the Assistant Secretary by the Secretary of Health and Human Services on March 28, 2001 (66 FR 18642), I rescinded the following delegation to the Director of ORR made on April 10, 2001 (66 FR 19960–61) and re-delegated the responsibilities to the Director of OTIP, with authority to re-delegate:

Authority to conduct certification activities under section 107(b)(1) of the TVPA, (22 U.S.C. 7105(b)(1)). In exercising this authority, personnel in OTIP will consult with the Secretary of Homeland Security.

By virtue of the authority vested in the Assistant Secretary by the Secretary of Health and Human Services on March 23, 2009 (74 FR 14564), I rescinded the following delegations to the Director of ORR made on April 10, 2009 (74 FR 19233) and re-delegated the responsibilities to the Director of OTIP, with authority to re-delegate:

Authority under section 107(b)(1) of the TVPA (22 U.S.C. 7105(b)(1)) to provide interim assistance to children who may have been subjected to a severe form of trafficking and to issue eligibility letters and conduct related activities. In issuing eligibility letters, personnel in the Administration for Children and Families will consult with the Attorney General, the Secretary of Homeland Security, and nongovernmental organizations with expertise on victims of trafficking.

Authority to train Federal staff and State and local officials to improve identification and protection for victims of a severe form of trafficking under section 107(c)(4) of the TVPA (22 U.S.C. 7105(c)(4)).

These delegations of authority supersede any prior delegations or re-delegations on these subjects to the extent such delegations or re-delegations may be inconsistent herewith.

I hereby affirm and ratify any actions taken by the Director of Refugee Resettlement and the OTIP Director, or his or her subordinates, which involved the exercise of authorities prior to the effective date of these January 27, 2016, delegations.

These authorities shall be exercised under the Department's policy on regulations and the existing delegation of authority to approve and issue regulations.

These delegations shall be exercised under financial and administrative requirements applicable to these Administration for Children and Families authorities.

The delegations listed were effective January 27, 2016.

Dated: May 12, 2016.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2016–11731 Filed 5–17–16; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on June 28, 2016, from 8 a.m. to 5 p.m.

ADDRESSES: Hilton Washington DC/Rockville Hotel & Executive Meeting Center, Plaza Ballroom, 1750 Rockville Pike, Rockville, MD 20852. The hotel's telephone number is 301–468–1100. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *EMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss supplemental new drug application (sNDA) 204629, empagliflozin (JARDIANCE) tablets, and sNDA 206111, empagliflozin and metformin hydrochloride (SYNJARDY) tablets. Both sNDAs are sponsored by Boehringer Ingelheim Pharmaceuticals, Inc., for the proposed additional indication in adult patients with type 2 diabetes mellitus and high cardiovascular risk to reduce the risk of all-cause mortality by reducing the incidence of cardiovascular death and to reduce the risk of cardiovascular death or hospitalization for heart failure.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 14, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 6, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 7, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact LaToya Bonner at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 11, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–11678 Filed 5–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces

plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than July 18, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14A39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Teaching Health Center Graduate Medical Education (THCGME) Program Eligible Resident/Fellow FTE Chart OMB 0915–0367—REVISION

Abstract: The Teaching Health Center Graduate Medical Education (THCGME) Program, Section 340H of the Public Health Service (PHS) Act, was established by Section 5508 of Public Law 111–148. Public Law 114–10, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) provided continued funding for the THCGME Program. The THCGME Program awards payment for both direct and indirect expenses to support training for primary care residents in community-based ambulatory patient care settings. The THCGME Program Eligible Resident/Fellow FTE Chart, published in the THCGME Funding Opportunity Announcements (FOAs), is a means for determining the number of eligible resident/fellow full-time equivalents (FTEs) in an applicant's primary care residency program. The current THCGME Program Eligible Resident/Fellow FTE Chart received OMB clearance on September 16, 2013. HRSA is revising the chart to provide clearer projections over a longer period of time.

Need and Proposed Use of the Information: The THCGME Program Eligible Resident/Fellow FTE Chart requires applicants to provide data related to the size and/or growth of the residency program over previous academic years, the number of residents enrolled in the program during the baseline academic year, and a projection of the program's proposed expansion over the next 5 academic years. It is imperative that applicants complete this chart and provide evidence of a planned expansion, as per the statute, THCGME funding may only be used to support an expanded number of residents in a residency program or to establish a new residency training program. Utilization of a chart to gather this important information has decreased the number of errors in the eligibility review process resulting in a more accurate review and funding process. In the proposed revisions, the content of the information collected has not changed; however, the order in which the information is presented on the chart has been modified to provide clearer projections over a longer period of time. This extended time frame would allow programs the flexibility to project the variations that occur during the natural expansion and scaling up of residency programs. This would better equip HRSA to make more accurate future funding projections.

Likely Respondents: Teaching Health Centers applying for THCGME funding through a THCGME FOA, which may include new applicants and existing awardees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and, to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Teaching Health Center GME Program Eligible Resident/Fellow FTE Chart	90	1	90	0.5	45
Total	90		90		45

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–11657 Filed 5–17–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than July 18, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N–39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915–0310—Revision.

Abstract: The Stem Cell Therapeutic and Research Act of 2005, Public Law (P.L.) 109–129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2015, P.L. 114–104 (the Act), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. HRSA's Healthcare Systems Bureau has established the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain record keeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation under contract to the U.S. Department of Health and Human Services (HHS). The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using a standardized, electronic format. Data is collected from transplant centers by the Center for International Blood and Marrow Transplant Research and is used for ongoing analysis of transplant outcomes. The increase in burden is due to an increase in the annual number of transplants and increasing survivorship after transplantation.

Need and Proposed Use of the Information: HRSA uses the information to carry out its statutory responsibilities. Information is needed to monitor the clinical status of transplantation and provide the Secretary of HHS with an annual report of transplant center-specific survival data.

Likely Respondents: Transplant Centers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized Burden Hours:

	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Baseline Pre-Transplant Essential Data (TED)	200	44	8,800	1.15	10,120
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	33	6,600	1	6,600
100-Day Post-TED	200	44	8,800	1	8,800
6-Month Post-TED	200	36	7,200	1.15	8,280
12-Month Post-TED	200	32	6,400	1.15	7,360
Annual Post-TED	200	110	22,000	1.15	25,300
* Total	200		59,800		66,460

* The Total of 200 is the number of centers completing the form. The same group of 200 centers completes each of the forms.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–11674 Filed 5–17–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than June 17, 2016.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to

OIRA_submission@omb.eop.gov or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rural Network Allied Health Training Program Performance Improvement Measurement System (PIMS)

OMB No.: 0906–xxxx—NEW.

Abstract: The Rural Network Allied Health Training Program will support the development of formal, mature rural health networks that focus on activities that achieve efficiencies, expand access to, coordinate and improve the quality of essential health care services, and strengthen the rural health care system as a whole. This purpose will be achieved through the recruitment, clinical training, and retention of allied health professionals.

This program will further support integrated rural health networks that can partner with local community colleges and other accredited educational institutions (such as vocational and technical colleges) to develop formal clinical training programs.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993. These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP), including: (a) Access to care; (b) population demographics; (c) staffing; (d) consortium/network; (e) sustainability; and (f) project specific domains. Several measures will be used for this program. All measures will speak to FORHP's progress toward meeting the goals.

Likely Respondents: The respondents are recipients of the Rural Network Allied Health Training Program grant funding.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Rural Network Allied Health Training Program Performance Measures	10	1	10	6.55	65.5
Total	10		10		65.5

Jason E. Bennett,
Director, Division of the Executive Secretariat.

[FR Doc. 2016–11672 Filed 5–17–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive License: The Development of an Anti-GPC3 Chimeric Antigen Receptor (CAR) Based on HN3 for the Treatment of Human Cancers

AGENCY: National Institutes of Health, Public Health Service, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in:

Intellectual Property: U.S. Provisional Patent Application 61/654,232 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E–136–2012/0–US–01]; PCT Patent Application PCT/US2013/043633 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E–136–2012/0–PCT–02]; Chinese Patent Application 201380039993.7 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E–136–2012/0–CN–03]; Japanese Patent Application 2015–515243 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E–136–2012/0–JP–04]; South Korea Patent Application 10–2014–7037046 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E–136–2012/0–KR–05]; Singapore Patent Application 11201407972R entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E–136–2012/0–SG–06]; United States Patent Application 14/403,896 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E–136–2012/0–US–07]; and all continuing U.S. and foreign patents/patent applications for the technology family, to Lentigen Technology, Inc.

The patent rights to these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive licensed territory may be the United States, Australia, Canada, the European Union, Russia, China, Hong Kong, Japan, Taiwan, South Korea and Singapore, and the field of use may be limited to: "The development of a glypican-3 (GPC3) chimeric antigen receptor (CAR)-based immunotherapy using autologous (meaning one individual is both the donor and the recipient) primary human lymphocytes (T cells or NK cells) transfected with a lentiviral or retroviral vector, wherein the vector expresses a CAR having (1) a single antigen specificity and (2) comprising at least: (a) the complementary determining region (CDR) sequences of the anti-GPC3 antibody known as HN3; and (b) a T cell signaling domain; for the prophylaxis and treatment of GPC3-expressing cancers."

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before June 2, 2016 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, National Cancer Institute, 9609 Medical Center Drive, Rm 1–E530 MSC9702, Rockville, MD 20850–9702, Email: *david.lambertson@nih.gov.*

SUPPLEMENTARY INFORMATION: This invention concerns an anti-GPC3 (Glypican-3) chimeric antigen receptor (CAR) and methods of using the CAR for the treatment of GPC3-expressing cancers. GPC3 is a cell surface antigen that is preferentially expressed on certain types of cancer cells, particularly liver cancers such as hepatocellular carcinoma (HCC). The anti-GPC3 CARs of this technology contain (1) antigen recognition sequences that bind specifically to GPC3 and (2) signaling domains that can activate the cytotoxic functions of a T cell. The anti-GPC3 CAR can be transduced into T cells that are harvested from a donor, followed by (a) selection and expansion of the T cells expressing the anti-GPC3 CAR, and (b) reintroduction of the T cells into the patient. Once the anti-GPC3 CAR-expressing T cells are reintroduced into the patient, the T cells can selectively bind to GPC3-expressing cancer cells through its antigen recognition sequences, thereby activating the T cell through its signaling domains to selectively kill the cancer cells. Through this mechanism of action, the selectivity of the a CAR allows the T cells to kill cancer cells while leaving healthy, essential cells unharmed. This can result in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive start-up option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 12, 2016.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016–11659 Filed 5–17–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Survey To Assess the Feasibility of Establishing a Gynecologic Specimen Bank (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute, the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 8, 2016 page 12111 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Goli Samimi, Program Director, Breast and Gynecologic Cancer Research Group, Division of Cancer Prevention. 9609 Medical Center Drive, MSC 9783, Bethesda, MD 20892, or call non-toll-free number (240) 276–6582, or Email your request, including your address to: *goli.samimi@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Survey to assess the feasibility of establishing a gynecologic specimen bank (NCI), 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute is assessing the feasibility of developing a tissue bank that would include tube and ovary tissues from women undergoing surgery for benign conditions, risk reduction and early stage cancer. Collecting tissues from tubes and ovaries containing clinically unsuspected precursors or early stage cancer is challenging, especially among women that are not at increased genetic risk. However, given that many pathology laboratories have enhanced their processing protocols for gynecologic surgical specimens removed for benign indications, it may be possible to develop a tissue resource. Accordingly, we are requesting information via a survey about the volume of samples that are accessioned at different pathology laboratories, and the methods used to process these samples. These data would provide information necessary to assess the feasibility of establishing a tissue bank for research and provide insights into the best design of a pilot study.

OMB approval is requested for 1 year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 42 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Category of respondent	Form name	Number of respondents	Frequency of response per respondent	Time per response (in hours)	Burden hours
Lab Managers	Survey	250	1	10/60	42

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Category of respondent	Form name	Number of respondents	Frequency of response per respondent	Time per response (in hours)	Burden hours
Totals		250			42

Dated: May 7, 2016.

Karla Bailey,

Project Clearance Liaison, National Cancer Institute, NIH.

[FR Doc. 2016–11658 Filed 5–17–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Community Influences on Health Behavior Study Section.

Date: June 9–10, 2016.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Westin Grand, 2350 M Street NW., Washington, DC 20037.

Contact Person: Wenchi Liang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3150, MSC 7770, Bethesda, MD 20892, 301–435–0681, *liangw3@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group; Vaccines Against Microbial Diseases Study Section.

Date: June 9–10, 2016.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Jian Wang, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4218, MSC 7812, Bethesda, MD 20892, (301) 435–2778, *wangjia@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies, Integrated Review Group; Biomedical Computing and Health Informatics Study Section.

Date: June 9–10, 2016.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Peter J Kozel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, Bethesda, MD 20892, 301–435–1116, *kozelp@mail.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Arthritis, Connective Tissue and Skin Study Section.

Date: June 14–15, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Alexey Belkin, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge DR Rm 4102, Bethesda, MD 20817, 301–435–3578, *alexey.belkin@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cancer Drug Development and Therapeutics.

Date: June 14–15, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Lilia Topol, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, 301–451–0131, *ltopol@mail.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience, Integrated Review Group; Clinical Neuroscience and Neurodegeneration Study Section.

Date: June 14–15, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Washington, 1515 Rhode Island Ave NW., Washington, DC 20005.

Contact Person: Alessandra C Rovescalli, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm 5205 MSC 7846, Bethesda, MD 20892, (301) 435–1021, *rovescaa@mail.nih.gov.*

Name of Committee: Vascular and Hematology Integrated Review Group; Hemostasis and Thrombosis Study Section.

Date: June 14, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Bukhtiar H Shah, Ph.D., DVM, Scientific Review Officer, Vascular and Hematology IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, (301) 806–7314, *shahb@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Collaborative Applications: Child Psychopathology.

Date: June 14, 2016.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Best Western Tuscan Inn, 425 North Point Street, San Francisco, CA 94133.

Contact Person: Jane A Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445, *doussarj@csr.nih.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Tumor Progression and Metastasis Study Section.

Date: June 15–16, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Solamar, 435 6th Avenue, San Diego, CA 92101.

Contact Person: Rolf Jakobi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7806, Bethesda, MD 20892, 301–495–1718, *jakobir@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cancer Diagnostics and Treatments (CDT).

Date: June 15–16, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Zhang-Zhi Hu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186, MSC 7804, Bethesda, MD 20892, (301) 594–2414, *huzhuang@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology, Integrated Review Group; Clinical Research and Field Studies of Infectious Diseases Study Section.

Date: June 15–16, 2016.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Mclean Tysons Corner, 7920 Jones Branch Dr., Mclean, VA 22102.

Contact Person: Soheyla Saadi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301–435–0903, *saadisoh@csr.nih.gov.*

Name of Committee: Center for Scientific, Review Special Emphasis Panel; Small Business Orthopedic, Skeletal Muscle, and Oral Sciences.

Date: June 15–16, 2016.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Aftab A. Ansari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, 301–237–9931, *ansaria@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Cellular Mechanisms in Aging and Development Study Section.

Date: June 16–17, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: John Burch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3213, MSC 7808, Bethesda, MD 20892, 301–408–9519, *burchjb@csr.nih.gov.*

Name of Committee: Center for Scientific, Review Special Emphasis Panel; Small Business: Computational, Modeling, and Biodata Management.

Date: June 16, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Allen Richon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, 301–379–9351, *allen.richon@nih.hhs.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Biology Structure and Regeneration Study Section.

Date: June 16–17, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202.

Contact Person: Daniel F McDonald, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4110, MSC 7814, Bethesda, MD 20892, (301) 435–1215, *mcdonald@csr.nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Electrical Signaling, Ion Transport, and Arrhythmias Study Section.

Date: June 16, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Chee Lim, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 4128, Bethesda, MD 20892, 301–435–1850, *limc4@csr.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Oral, Dental and Craniofacial Sciences Study Section.

Date: June 16–17, 2016.

Time: 8:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Virginia Suites, 1500 Arlington Blvd., Arlington, VA 22209.

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, *liuyh@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Biophysical, Physiological, Pharmacological and Bioengineering Neuroscience.

Date: June 16, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Washington, 1515 Rhode Island Ave, NW., Washington, DC 20005.

Contact Person: Paula Elyse Schauwecker, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 5211, Bethesda, MD 20892, *schauweckerpe@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Synapses, Cytoskeleton and Trafficking Study Section.

Date: June 16–17, 2016.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Clayton Plaza Hotel, 7730 Bonhomme Ave, St. Louis, MO 63105.

Contact Person: Christine A. Piggee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4186, MSC 7850, Bethesda, MD 20892, 301–435–0657, *christine.piggee@nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience, Integrated Review Group; Molecular Neuropharmacology and Signaling Study Section.

Date: June 16–17, 2016

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Seattle Hotel, 1400 6th Ave, Seattle, WA 98101.

Contact Person: Deborah L. Lewis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4183, MSC 7850, Bethesda, MD 20892, 301–408–9129, *lewisdeb@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience, Integrated Review Group; Neural Oxidative Metabolism and Death Study Section.

Date: June 16–17, 2016.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213–9887, *hamelinc@csr.nih.gov.*

Name of Committee: Cell Biology, Integrated Review Group; Biology of the Visual System Study Section.

Date: June 16–17, 2016.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Michael H. Chaitin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7850, Bethesda, MD 20892, (301) 435–0910, *chaitinm@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Molecular Genetics A Study Section.

Date: June 16–17, 2016.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance M Street Hotel, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Michael M. Sveda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1114, MSC 7890, Bethesda, MD 20892, 301–435–3565, *svedam@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genetics of Health and Disease Study Section.

Date: June 16–17, 2016.

Time: 8:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Lorien Hotel & Spa, 1600 King Street, Alexandria, VA 22314.

Contact Person: Cheryl M Corsaro, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2204, MSC 7890, Bethesda, MD 20892, (301) 435–1045, *corsaroc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Electrical Signaling, Ion Transport and Arrhythmias Special Panel.

Date: June 16, 2016.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Abdelouahab Aitouche, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4222, MSC 7814, Bethesda, MD 20892, 301–435–2365, *aitouchea@csr.nih.gov.*

Name of Committee: Center for Scientific Review, Special Emphasis Panel; SBIB Clinical Pediatric and Fetal Applications.

Date: June 16, 2016.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: John Firrell, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5118, MSC 7854, Bethesda, MD 20892, 301–435–2598, *firrellj@csr.nih.gov.*

Name of Committee: Center for Scientific Review, Special Emphasis Panel, Member Conflict: Neural Trauma and Neurovascular Pathology.

Date: June 17, 2016.

Time: 1:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alexei Kondratyev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301–435–1785, *kondratyevad@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 12, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–11662 Filed 5–17–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-up Exclusive License: Development of Virus Like Particles for the Treatment of Breast Cancer, Lung Cancer, Melanoma, Pancreatic Cancer, and Hepatocellular Cancer

AGENCY: National Institutes Of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7, that the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Patent License to practice the inventions embodied in the following patent applications to Chimeron Bio Corporation, a company incorporated under the laws of Delaware and having an office in Philadelphia, PA.

Intellectual Property: U.S. Provisional Patent Application No.: 61/615,687 Entitled "Delivery of Packaged RNA in Mammalian Cells" HHS Ref. No.: E–264–2011/0–US–01 Filed March 26, 2012; International Patent Application No.: PCT/US2013/031876 Entitled "Delivery of Packaged RNA in Mammalian Cells" HHS Ref. No.: E–264–2011/0–PCT–02 Filed March 15, 2013; Australian Patent Application No.: 2013–240248 Entitled "Delivery of Packaged RNA in Mammalian Cells" HHS Ref. No.: E–264–2011/0–AU–03 Filed October 17, 2014; European Patent Application No.: 13712661.1 Entitled "Delivery of Packaged RNA in Mammalian Cells" HHS Ref. No.: E–264–2011/0–EP–04 Filed October 24, 2014; Japanese Patent Application No.: 2015–503322 entitled "Delivery of Packaged RNA in Mammalian Cells" HHS Ref. No.: E–264–2011/0–JP–05 Filed September 25, 2014; U.S. Patent Application No.: 14/388,441 Entitled Delivery of Packaged RNA in Mammalian Cells" HHS Ref. No.: E–264–2011/0–US–06 Filed September 26, 2014; U.S. Provisional Patent Application No.: 61/916,394 Entitled "Cancer Immunotherapy: Delivery HLA–11 using VLP-Replicon" HHS Ref. No.: E–050–2014/0–US–01 Filed December 16, 2013; International Patent Application No.: PCT/US2014/070552 Entitled "Cancer Immunotherapy: Delivery HLA–11 using VLP-Replicon" HHS Ref. No.: E–050–2014/0–PCT–02 Filed December 16, 2014;

The patent rights to these inventions have been assigned to the Government of the United States of America.

The prospective exclusive start-up licensed territory may be worldwide and the field of use may be limited to: "Use of virus like particles comprising MHCII and CD80 for the treatment of breast cancer, lung cancer, melanoma, pancreatic cancer, and hepatocellular cancer."

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before June 2, 2016 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Lauren Nguyen-Antczak, Ph.D., J.D., Sr. Licensing and Patenting Manager, Technology Transfer Center, National Cancer Institute, 8490 Progress Drive, Riverside 5, Suite 400, Frederick, MD 21701; Telephone: (301) 624–8752; Email: *lauren.nguyen-antczak@nih.gov.*

SUPPLEMENTARY INFORMATION: The invention is directed to virus-like particles ("VLPs") that serve to induce transgene expression of at least one recombinant protein of interest in specific, targeted cells. This technology can be used to treat a variety of diseases, depending on the cell type to be targeted. Preferably, invention VLPs may be used to treat tumor bearing cancers, including breast cancer, lung cancer, melanoma, pancreatic cancer, and hepatocellular cancer.

The prospective Start-Up Exclusive Patent License, which will be royalty bearing, is being considered under the small business initiative launched on 1 October 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective Start-Up Exclusive Patent License may be granted unless the NIH receives written evidence and argument, within fifteen (15) days from the date of this published notice, that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive start-up license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 12, 2016.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016–11661 Filed 5–17–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; NIDCR Data Analysis and Statistical Methodology PARs.

Date: June 10, 2016.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892.

Contact Person: Victor Henriquez, Ph.D., Scientific Review Officer DEA/SRB/NIDCR, 6701 Democracy Blvd., Room 668, Bethesda, MD 20892–4878, 301–451–2405, *henriquv@nidcr.nih.gov.*

Name of Committee: NIDCR Special Grants Review Committee.

Date: June 16–17, 2016.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham San Antonio Riverwalk 111 East Pecan Street, San Antonio, TX 78205

Contact Person: Marilyn Moore-Hoon, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Rm. 676, Bethesda, MD 20892–4878, 301–594–4861, *mooremar@nidcr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: May 12, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–11663 Filed 5–17–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive License: The Development of an Anti-GPC3 Chimeric Antigen Receptor (CAR) Based on YP7 for the Treatment of Human Cancers

AGENCY: Public Health Service, National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in:

Intellectual Property

U.S. Provisional Patent Application 61/654,232 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E–136–2012/0–US–01]; PCT Patent Application PCT/US2013/043633 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E–136–2012/0–PCT–02]; Chinese Patent Application 201380039993.7 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E–136–2012/0–CN–03]; Japanese Patent Application 2015–515243 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E–136–2012/0–JP–04]; South Korea Patent Application 10–2014–7037046 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E–136–2012/0–KR–05]; Singapore Patent Application 11201407972R entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E–136–2012/0–SG–06]; United States Patent Application 14/403,896 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E–136–2012/0–US–07];

and all continuing U.S. and foreign patents/patent applications for the technology family, to Lentigen Technology, Inc.

The patent rights to these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive licensed territory may be the United States, Australia, Canada, the European Union, Russia, China, Hong Kong, Japan, Taiwan, South Korea and Singapore, and the field of use may be limited to: "The development of a glypican-3 (GPC3) chimeric antigen receptor (CAR)-based immunotherapy using autologous (meaning one individual is both the donor and the recipient) primary human lymphocytes (T cells or NK cells) transfected with a lentiviral or retroviral vector, wherein the vector expresses a CAR having (1) a single antigen specificity and (2) comprising at least: (a) The complementary determining region (CDR) sequences of the anti-GPC3 antibody known as YP7; and (b) a T cell signaling domain; for the prophylaxis and treatment of GPC3-expressing cancers."

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before June 2, 2016 will be considered.

ADDRESSEES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, National Cancer Institute, 9609 Medical Center Drive, Rm 1–E530 MSC9702, Rockville, MD 20850–9702, Email: *david.lambertson@nih.gov.*

SUPPLEMENTARY INFORMATION: This invention concerns an anti-GPC3 (Glypican-3) chimeric antigen receptor (CAR) and methods of using the CAR for the treatment of GPC3-expressing cancers. GPC3 is a cell surface antigen that is preferentially expressed on certain types of cancer cells, particularly liver cancers such as hepatocellular carcinoma (HCC). The anti-GPC3 CARs of this technology contain (1) antigen recognition sequences that bind specifically to GPC3 and (2) signaling domains that can activate the cytotoxic functions of a T cell. The anti-GPC3 CAR can be transduced into T cells that are harvested from a donor, followed by (a) selection and expansion of the T cells expressing the anti-GPC3 CAR, and (b) reintroduction of the T cells into the patient. Once the anti-GPC3 CAR-expressing T cells are reintroduced into the patient, the T cells can selectively bind to GPC3-expressing cancer cells through its antigen recognition sequences, thereby activating the T cell through its signaling domains to selectively kill the cancer cells. Through this mechanism of action, the selectivity of the a CAR allows the T cells to kill cancer cells while leaving healthy, essential cells unharmed. This can result in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive start-up option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 12, 2016.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016–11660 Filed 5–17–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5913–N–10]

60-Day Notice of Proposed Information Collection: FHA Technology Open to Approved Lenders (TOTAL) Mortgage Scorecard

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date: July 18, 2016.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Kevin Stevens, 451 7th Street SW., Washington, DC 20410; email *Kevin L. Stevens@hud.gov;* or telephone 202–402–2673. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: FHA TOTAL Mortgage Scorecard.

OMB Approval Number: 2502–0556.

Type of Request: Extension of a currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: The regulation mandating this collection can be found in the Code of Federal Regulations at 24 CFR 203.255(b)(5). This information is necessary to assure that lenders (and automated underwriting system (AUS) vendors) are aware of their obligations regarding use of the TOTAL Mortgage Scorecard and are certifying that they will comply with all pertinent regulations. It also allows FHA to request reports from lenders regarding their use of the scorecard, that they have implemented appropriate quality control procedures for using the scorecard, and provides an appeal mechanism should FHA take an action to terminate a lender's use of the scorecard.

Respondents : Business or other for profit.

Estimated Number of Respondents: 2709.

Estimated Number of Responses: 100.

Frequency of Response: On occasion.

Average Hours per Response: .02.

Total Estimated Burdens: 100.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: May 12, 2016.

Janet M. Golrick,

Associate General Deputy Assistant Secretary for Housing Associate Deputy Federal Housing Commissioner.

[FR Doc. 2016–11742 Filed 5–17–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[16X LLUT920000 L13100000.DN0000 LXSSJ0540000 24 1A]

Notice of Intent To Prepare a Master Leasing Plan, Amend the Resource Management Plans for the Price and Richfield Field Offices, and Prepare an Associated Environmental Assessment, Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Price and Richfield Field Offices intend to prepare a Master Leasing Plan (MLP) and Resource Management Plan (RMP) amendments with a single Environmental Assessment (EA). The BLM will consider resource management plan decisions related to oil and gas leasing and post-leasing oil and gas development on approximately 525,000 acres of public land in the San Rafael Desert, located in Emery and

Wayne Counties, Utah. By this notice, the BLM is announcing the beginning of the scoping process to solicit public comments and identify issues.

DATES: This notice initiates the public scoping process for the San Rafael Desert MLP, RMP amendments, and associated EA. Comments on issues may be submitted in writing until the end of the scoping period, which is June 17, 2016. The date(s) and location(s) of any scoping meetings will be announced at least 15 days in advance through local news media, newspapers and the BLM Web site at: *http://www.blm.gov/ut/st/en.html.* In order to be included in the analysis, all comments must be received prior to the close of the 30-day scoping period or 15 days after the last public meeting, whichever is later. We will provide additional opportunities for public participation as appropriate.

ADDRESSES: Comments may be submitted on issues and planning criteria related to the San Rafael Desert MLP and RMP amendments/EA by any of the following methods:

- *Email: BLM_UT_PR_MAIL@blm.gov*
- *Fax:* (435) 636–3657
- *Mail:* BLM Price Field Office, 125 South 600 West, Price, UT 84501; Attention: Jake Palma

FOR FURTHER INFORMATION CONTACT: Tyler Ashcroft, National Project Manager; telephone (801) 539–4068; email *tashcrof@blm.gov.* Contact Mr. Ashcroft to have your name added to our mailing list. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. Replies are provided during normal business hours.

SUPPLEMENTARY INFORMATION: This document provides notice that the BLM Price and Richfield Field Offices in Utah intend to prepare an MLP and RMP amendments with a single EA for the San Rafael Desert, announces the beginning of the scoping process, and seeks public input on issues and planning criteria.

The planning area is located in Emery and Wayne counties in Utah and encompasses approximately 525,000 acres of public land that are primarily located south of Interstate 70 and east of Highway 24. The eastern boundary of the MLP planning area is generally the Green River. A small portion of the MLP area is located north of Interstate 70, west of the City of Green River, UT, and East of the San Rafael Swell. U.S. Highway 6 bisects this part of the planning area.

The BLM will prepare the MLP in accordance with Washington Office Instruction Memorandum No. 2010–117, Oil and Gas Leasing Reform—Land Use Planning and Lease Parcel Reviews, May 17, 2010, which has been incorporated and supplemented in various BLM handbooks, including H–1624–1, Planning for Fluid Mineral Resources. The MLP process will provide additional planning and analysis for areas prior to new leasing of oil and gas resources. The MLP process will enable the Price and Richfield Field Offices to: (1) Resolve long-standing lease protests relating to parcels of land for which BLM received lease offers subject to protest, but for which BLM has not issued leases in the planning area; (2) Determine whether the BLM should cancel, modify, or lift the suspensions on suspended leases in the planning area; (3) Evaluate potential development scenarios; (4) Identify and address potential resource conflicts and environmental impacts from development; (5) Create oil and gas development mitigation strategies; and (6) Consider a range of new conditions, including prohibiting surface occupancy or closing certain areas to leasing.

The MLP process could result in new oil and gas leasing stipulations and development scenarios which would require amendments to the Price and Richfield RMPs completed in 2008. The EA will analyze likely oil and gas development scenarios and land use plan alternatives with varying mitigation levels for leasing.

The purpose of the public scoping process is to determine relevant issues, identify alternatives, and guide the planning process. Preliminary issues for the plan amendment area have been identified by BLM personnel; Federal, State, and local agencies; and other stakeholders. The potential issues include: Air quality, climate change, cultural resources, paleontological resources, recreation, visual resources, night skies, riparian resources, soil and water resources, vegetation, wildlife resources, special status species, special designations, and wilderness characteristics.

The BLM established preliminary planning criteria for this effort. As part of those criteria, the BLM will: (1) Limit the scope to resource management plan decisions pertaining to oil and gas leasing and post-leasing development of the area; (2) resolve long-standing lease protests and decide whether to cancel, modify, or lift the suspension on suspended leases in the planning area; (3) recognize valid existing rights; (4) only address management of public lands (including federal mineral estate under non-federal surface in a "split estate" situation); (5) use a collaborative, multi-jurisdictional approach to determine how mineral leasing will be managed; (6) ensure that its management decisions are as consistent as possible with local, State, and other Federal agency plans; (7) prepare development scenarios for oil and gas resources based on historical, existing, and projected levels of development; (8) consider a range of alternatives that focus on mitigating the impacts of development on resources that are of concern; (9) address the socioeconomic impacts of the alternatives; and, (10) use the best available scientific information and inventory and monitoring information to determine appropriate decisions for oil and gas leasing.

You may submit comments on issues and planning criteria in writing to the BLM at any public scoping meeting, or you may submit them to the BLM using one of the methods listed in the **ADDRESSES** section above. To be most helpful, you should submit comments by the close of the 30-day scoping period or within 15 days after the last public meeting, whichever is later.

The BLM will utilize the NEPA scoping process to help fulfill the public involvement requirements under the National Historic Preservation Act (54 U.S.C. 306108), as provided in 36 CFR 800.2(d)(3). The information about historic and cultural resources within the area potentially affected by the proposed action will assist the BLM in identifying and evaluating impacts to such resources.

The BLM will consult with Indian tribes on a government-to-government basis in accordance with Executive Order 13175 and other policies. Tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration. Federal, State, and local agencies, along with tribes and other stakeholders that may be interested in or affected by the proposed action that the BLM is evaluating, are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate in the development of the EA as a cooperating agency.

The BLM will use an interdisciplinary approach to develop the plan amendment in order to consider the variety of resource issues and concerns identified. Specialists with expertise in the following disciplines will be involved in the planning process: Minerals and geology, outdoor recreation, visual resources management, Areas of Critical Environmental Concern (ACEC) and National Conservation Lands management, archaeology, paleontology, wildlife and fisheries, special status species, hydrology, soils, rangeland management, air quality, and sociology and economics.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1501.7 and 43 CFR 1610.2

Jenna Whitlock,
Acting State Director.

[FR Doc. 2016–11726 Filed 5–17–16; 8:45 am]

BILLING CODE 4310–DQ–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1315 (Preliminary)]

Ferrovanadium From Korea

Determination

On the basis of the record[1] developed in the subject investigation, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of ferrovanadium from Korea, provided for in subheading 7202.92.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value ("LTFV").

Commencement of Final Phase Investigation

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigation. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the Department of Commerce ("Commerce") of an affirmative preliminary determination in the investigation under section 733(b) of the Act, or, if the preliminary determination is negative, upon notice of an affirmative final determination in that investigation under section 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigation need not enter a separate appearance for the final phase of the investigation. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigation.

Background

On March 28, 2016, the Vanadium Producers and Reclaimers Association and its members AMG Vanadium, LLC, Cambridge, Ohio; Bear Metallurgical Company, Butler, Pennsylvania; Gulf Chemical & Metallurgical Corporation, Freeport, Texas; and Evraz Stratcor, Inc., Hot Springs, Arkansas, filed a petition with the Commission and Commerce, alleging that an industry in the United States is materially injured and threatened with material injury by reason of LTFV imports of ferrovanadium from Korea. Accordingly, effective March 28, 2016, the Commission, pursuant to section 733(a) of the Tariff Act of 1930 (19 U.S.C. § 1673b(a)), instituted antidumping duty investigation No. 731–TA–1315 (Preliminary).

Notice of the institution of the Commission's investigation and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of April 1, 2016 (81 FR 18888). The conference was held in Washington, DC, on April 18, 2016, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made this determination pursuant to section 733(a) of the Tariff Act of 1930 (19 U.S.C. § 1673b(a)). It completed and filed its determination in this investigation on May 12, 2016. The views of the Commission are contained in USITC Publication 4611 (May 2016), entitled *Ferrovanadium from Korea: Investigation No. 731–TA–1315 (Preliminary).*

By order of the Commission.

Issued: May 12, 2016.

Lisa R. Barton,
Secretary to the Commission.

[FR Doc. 2016–11668 Filed 5–17–16; 8:45 am]

BILLING CODE 7020–02–P

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[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR § 207.2(f)).

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–890]

Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof; Commission's Determination To Suspend Remedial Orders Issued in This Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to suspend the limited exclusion order and cease and desist orders issued in this investigation pending remand proceedings.

FOR FURTHER INFORMATION CONTACT: Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–3042. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on August 23, 2013, based on a complaint filed by ResMed Corporation of San Diego, California; ResMed Incorporated of San Diego, California; and ResMed Limited of New South Wales, Australia (collectively, "ResMed"). 78 FR 52564 (Aug. 23, 2013). The complaint alleged violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the

United States after importation of certain sleep-disordered breathing treatment systems and components thereof that infringe one or more of claims 32–37, 53, 79, 80, and 88 of U.S. Patent No. 7,997,267 ("the '267 patent"); claims 1–7 of U.S. Patent No. 7,614,398 ("the '398 patent"); claim 1 of U.S. Patent No. 7,938,116 ("the '116 patent"); claims 30, 37, and 38 of U.S. Patent No. 7,341,060 (the '060 patent); claims 1, 3, 5, 11, 28, 30, 31, and 56 of U.S. Patent No. 8,312,883 ("the '883 patent"); claims 1, 3, 6, 7, 9, 29, 32, 35, 40, 42, 45, 50, 51, 56, 59, 89, 92, 94, and 96 of U.S. Patent No. 7,178,527 (the '527 patent); claims 19–24, 26, 29–36, and 39–41 of U.S. Patent No. 7,950,392 (the '392 patent); and claims 13, 15, 16, 26–28, 51, 52, and 55 of U.S. Patent No 7,926,487 ("the '487 patent"). The notice of investigation named the following respondents: BMC Medical Co., Ltd. of Beijing, China; 3B Medical, Inc. of Lake Wales, Florida; and 3B Products, L.L.C., of Lake Wales, Florida (collectively "BMC"). The Office of Unfair Import Investigations ("OUII") participated in the investigation.

On January 9, 2014, the Administrative Law Judge ("ALJ") issued an initial determination ("ID") granting a motion by ResMed to amend the complaint and notice of investigation to substitute U.S. Patent No. RE 44,453 ("the '453 patent") for the '398 patent and to terminate the investigation as to the '398 patent. *See* Order No. 7 (Jan. 9, 2014). The Commission determined not to review the ID. *See* Commission Notice of Non-Review (Feb. 10, 2014); 79 FR 9000–01 (Feb. 14, 2014).

On February 24, 2014, the ALJ issued an ID granting a motion by ResMed to withdraw its allegations with respect to the '116 patent. *See* Order No. 11 (Feb. 24, 2014). The Commission determined not to review the ID. *See* Commission Notice of Non-Review (March 11, 2014). On March 18, 2014, the ALJ granted a motion by ResMed to terminate the investigation as to claims 26–28 of the '487 Patent. *See* Order No. 20 (Mar 18, 2012). The Commission determined not to review the ID. *See* Commission Notice of Non-Review (Apr. 29, 2014).

On August 21, 2014, the ALJ issued his final ID, finding a violation of section 337 by BMC with respect to certain asserted claims of the '392, '267, '060, '883, '527, and '453 patents. The ALJ found no violation of section 337 with respect to the asserted claims of the '487 patent.

On September 3, 2014, the parties filed petitions for review of the ID. On September 11, 2014, the parties filed responses to the petitions for review.

On October 16, 2014, the Commission determined to review the final ID in part. 79 FR 63163–65 (Oct. 22, 2014). On review, the Commission determined to affirm the ALJ's finding of violation of section 337. The Commission, however, found the '453 patent invalid for anticipation. Having found a violation of section 337, the Commission determined that the appropriate form of relief was (1) a limited exclusion order prohibiting the unlicensed entry of sleep-disordered breathing treatment systems and components thereof that infringe one or more of claims 1, 9, 32, 89, and 92 of the '527 patent; claims 19, 21, 29, 32, and 36 of the '392 patent; claims 32, 33, 34, and 53 of the '267 patent; claims 30, 37, and 38 of the '060 patent; and claims 1, 3, 5, 11, 28, 30, 31, and 56 of the '883 patent that are manufactured by, or on behalf of, or are imported by or on behalf of BMC Medical Co., Ltd., 3B Medical, Inc., or 3B Products L.L.C. or any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns, except for service and replacement parts for customers that purchased their covered products prior to the date the exclusion order becomes final; and (2) cease and desist orders prohibiting domestic respondents BMC Medical Co., Ltd., 3B Medical, Inc. from conducting any of the following activities in the United States: Importing, selling, marketing, advertising, distributing, transferring (except for exportation), and soliciting U.S. agents or distributors for, sleep-disordered breathing treatment systems and components thereof covered by claims 1, 9, 32, 89, and 92 of the '527 patent; claims 19, 21, 29, 32, and 36 of the '392 patent; claims 32, 33, 34, and 53 of the '267 patent; claims 30, 37, and 38 of the '060 patent; and claims 1, 3, 5, 11, 28, 30, 31, and 56 of the '883 patent.

On February 18, 2015, ResMed filed a notice of appeal in the U.S. Court of Appeals for the Federal Circuit, seeking review of the Commission's determination as to the '453 patent (Appeal No. 2015–1360). On April 14, 2015, BMC filed a notice of appeal in the Federal Circuit, seeking review of the Commission's domestic industry determination as well as the Commission's finding that prior art does not render the asserted claims of the '267 patent invalid for obviousness (Appeal No. 2015–1576). The Court consolidated the two appeals on April 23, 2015.

On March 16, 2016, the parties jointly moved to dismiss ResMed's appeal as to the '453 patent. On March 17, 2016, the Commission moved to remand BMC's appeal in light of intervening domestic industry precedent in *Lelo Inc.* v. *International Trade Commisson,* 789 F.3d 879 (Fed. Cir. 2015). On March 29, 2016, the Court granted the motion dismiss ResMed's appeal. On April 22, 2016, the Court granted the Commission's remand motion, noting the Commission's indication that it would suspend its remedial orders as it conducts its remand proceedings.

The Commission has determined to suspend the remedial orders issued in this investigation pending the outcome of the remand.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: May 12, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–11638 Filed 5–17–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–997]

Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on April 14, 2016, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of ResMed Corp. of San Diego, California; ResMed Inc. of San Diego, California; and ResMed Ltd. of Australia. A corrected complaint was filed on April 18, 2016, and a supplement was filed on April 19, 2016. The corrected complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain sleeping-disordered breathing treatment systems and components thereof by reason of infringement of certain claims of U.S. Patent No. RE44,453 ("the '453 patent"); U.S. Patent No. 8,020,551 ("the '551 patent"); U.S. Patent No. 8,006,691 ("the '691 patent"); and U.S. Patent No. 9,072,860 ("the '860 patent"). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2015).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on May 11, 2016, *ordered that—*

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain sleeping-disordered breathing treatment systems and components thereof by reason of infringement of one or more of claims 23 and 24 of the '453 patent; claims 1–24 and 26–33 of the '551 patent; claims 1–31, 40–43, 52–59, 61–67, 69–84, 86–120, 122–158, 160, 161, 164, 165, 167, 168, and 173 of the '691 patent; and claims 16–30 of the '860 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

ResMed Corp., 9001 Spectrum Center Drive, San Diego, CA 92123
ResMed Inc., 9001 Spectrum Center Drive, San Diego, CA 92123
ResMed Ltd., 1 Elizabeth Macarthur Drive, Bella Vista NSW 2153, Australia

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

BMC Medical Co., Ltd., 5/F Main Building, No. 19 Gucheng Street West, Shijingshan, Beijing 100043, China
3B Medical, Inc., 21301 US Highway 27, Lake Wales, FL 33589
3B Products, L.L.C., 21301 US Highway 27, Lake Wales, FL 33589

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: May 12, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–11667 Filed 5–17–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–282 (Fourth Review)]

Petroleum Wax Candles from China

Determination

On the basis of the record[1] developed in the subject five-year review, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930, that revocation of the antidumping duty order on petroleum wax candles from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission, pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)), instituted this review on December 1, 2015 (80 FR 75130) and determined on March 7, 2016 that it would conduct an expedited review (81 FR 15122, March 21, 2016).

The Commission made this determination pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)). It completed and filed its determination in this review on May 12, 2016. The views of the Commission are contained in USITC Publication 4610 (May 2016), entitled *Petroleum Wax Candles from China: Investigation No. 731–TA–282 (Fourth Review).*

By order of the Commission.

Issued: May 12, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–11637 Filed 5–17–16; 8:45 am]

BILLING CODE 7020–02–P

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[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–943]

Certain Wireless Headsets; Commission Determination To Affirm With Modification an Initial Determination, Granting Respondents' Motion for Summary Determination of Patent Invalidity Due to Indefiniteness; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to affirm with certain modifications an initial determination ("ID") (Order No. 17), granting respondents' motion for summary determination of patent invalidity due to indefiniteness. The Commission finds no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337"). The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Megan M. Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–708–2301. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on January 13, 2015, based on a complaint filed by One-E-Way, Inc. of Pasadena, California ("One-E-Way"). 80 FR 1663 (Jan. 13, 2015). The complaint alleges violations of section 337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain wireless headsets by reason of infringement of certain claims of U.S. Patent Nos. 7,865,258 ("the '258 patent") and 8,131,391 ("the '391 patent"). *Id.* The notice of investigation named several respondents, including Sony Corporation of Tokyo, Japan; Sony Corporation of America of New York, New York; and Sony Electronics, Inc. of San Diego, California (collectively, "Sony"); Beats Electronics, LLC of Culver City, California and Beats Electronics International Ltd. of Dublin, Ireland (collectively, "Beats"); Sennheiser Electronic GmbH & Co. KG of Wedemark, Germany and Sennheiser Electronic Corporation of Old Lyme, Connecticut (collectively, "Sennheiser"); BlueAnt Wireless Pty, Ltd. of Richmond, Australia and BlueAnt Wireless, Inc. of Chicago, Illinois (collectively, "BlueAnt"); Creative Technology Ltd. of Singapore and Creative Labs, Inc. of Milpitas, California (collectively, "Creative Labs"); GN Netcom A/S d/b/a Jabra of Ballerup, Denmark ("GN Netcom"); and Jawbone, Inc. of San Francisco, California. *Id.* The Office of Unfair Import Investigations was also named as a party to the investigation. *Id.* The Commission previously terminated the investigation with respect to Beats and Sennheiser. See Notice (Apr. 29, 2015); Notice (June 11, 2015). The Commission also previously terminated the investigation with respect to certain claims of the '258 and '391 patents. *See* Notice (May 26, 2015); Notice (Aug. 26, 2015). On February 16, 2016, the Commission amended the Notice of investigation to correct the name of respondent Jawbone, Inc. to AliphCom d/b/a Jawbone, and also terminated the investigation as to AliphCom. Notice (Feb. 16, 2016).

On August 10, 2015, respondents Sony, BlueAnt, Creative Labs, and GN Netcom (collectively, "Respondents") filed a motion for summary determination that asserted claim 8 of the '258 patent and asserted claims 1, 3–6, and 10 of the'391 patent are invalid as indefinite under 35 U.S.C. 112, ¶ 2. On August 20, 2015, the Commission investigative attorney ("IA") filed a response in support of the motion. Also on August 20, 2015, One-E-Way filed an opposition to the motion. On August 27, 2015, Respondents moved for leave to file a reply to One-E-Way's opposition, which the presiding administrative law judge ("ALJ") granted that same day. *See* Order No. 16 (Aug. 27, 2015).

On September 21, 2015, the ALJ issued the subject ID (Order No. 17), granting Respondents' motion for summary determination that all of the asserted claims of the '258 and '391 patents are invalid as indefinite under 35 U.S.C. 112, ¶ 2 and finding no violation of section 337. On October 2, 2015, One-E-Way filed a petition for review of the subject ID. On October 9, 2015, Respondents and the IA each filed responses to the petition.

On December 1, 2015, the Commission determined to review Order No. 17 and posed several questions to the parties. 80 FR 76038–40 (Dec. 7, 2015). The parties filed initial submissions on December 11, 2015, and filed response submissions on December 18, 2015.

Having examined the record of this investigation, including the subject ID, the petitions for review, and the responses thereto, and the parties' submissions in response to the Commission's request for additional briefing, the Commission has determined to affirm Order No. 17 with modification. In particular, the Commission corrects the statement on pages 7, 61, and 65–66 of the subject ID that the limitations "free from interference" and "virtually free from interference" coexist in the asserted claims. The asserted claims recite the limitation "virtually free from interference" only. The Commission also clarifies that the ALJ's statement on page 85 of subject ID that the intrinsic evidence fails to explain how the invention both "transmits" and "reproduces" audio "virtually free from interference" should be made with reference to claims 1 and 5 of the '391 patent, not to claims 1 and 3 of the '391 patent.

The Commission finds no violation of section 337. The investigation is terminated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: May 12, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–11670 Filed 5–17–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–967]

Certain Document Cameras and Software for Use Therewith; Commission's Determination Not To Review an Initial Determination Terminating Recordex USA, Inc.; Request for Written Submissions on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's ("ALJ") initial determination ("ID") (Order No. 19) terminating Recordex USA, Inc. The Commission requests written submissions, under the schedule set forth below, on remedy, public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Amanda Pitcher Fisherow, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2737. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on September 24, 2015, based on a complaint filed on behalf of Pathway Innovations & Technologies, Inc. of San Diego, California ("Complainant"). 80 FR 57642 (September 24, 2015). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the sale for importation, importation, or sale within the United States after importation of certain document cameras and software for use therewith by reason of infringement of certain claims of U.S. Design Patent No. D647,906; U.S. Design Patent No. D674,389; U.S. Design Patent No. D715,300; and U.S. Patent No. 8,508,751. The Commission's notice of investigation named the following respondents: Recordex USA, Inc., of Long Island City, New York ("Recordex"); QOMO HiteVision, LLC, of Wixom, Michigan ("QOMO"); and Adesso, Inc. of Walnut, California ("Adesso"). The Office of Unfair Import Investigations was named as a party but has subsequently withdrawn from the investigation. Adesso was terminated based on a consent order stipulation and consent order. Order No. 5 (unreviewed) (Nov. 23, 2015). QOMO was found to be in default. Order No. 10 (unreviewed) (Dec. 7, 2015). Recordex is the last remaining respondent in this investigation.

On April 11, 2016, Complainant and Recordex filed a joint motion to terminate the investigation as to Recordex based on a settlement agreement. Complainant and Recordex stated that other than the settlement agreement, "[t]here are no other agreements, written or oral, express or implied between the moving parties concerning the subject matter of the investigation."

On April 20, 2016, the ALJ granted the joint motion. The ID agreed with Complainant and Recordex that termination of the investigation as to Recordex will not negatively impact the public interest. ID at 2. The parties provided public and confidential versions of the settlement agreement.

The Commission has determined not to review the subject ID.

As noted above, QOMO was previously found to be in default. Section 337(g)(1) and Commission Rule 210.16(c) authorize the Commission to order relief against a respondent found in default, unless, after considering the public interest, it finds that such relief should not issue. Complainant seeks a limited exclusion order and a cease and desist order.

In connection with the final disposition of this investigation, the Commission may: (1) Issue an order that could result in the exclusion of articles manufactured or imported by the defaulting respondent; and/or (2) issue a cease and desist order that could result in the defaulting respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (December 1994).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors that the Commission will consider include the effect that the exclusion order and/or cease and desists orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Complainant is also requested to state the date that the asserted patents expire and the HTSUS numbers under which the accused products are imported. Complainant is further requested to supply the names of known importers of the products at issue in this investigation.

The written submissions and proposed remedial orders must be filed no later than close of business on May 23, 2016. Reply submissions must be filed no later than the close of business on May 31, 2016. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337–TA–967") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with the any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: May 13, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–11706 Filed 5–17–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Heterogeneous System Architecture Foundation

Notice is hereby given that, on April 12, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Heterogeneous System Architecture Foundation ("HSA Foundation") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Mälardalen högskola, Västerås, SWEDEN, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and HSA Foundation intends to file additional written notifications disclosing all changes in membership.

On August 31, 2012, HSA Foundation filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on October 11, 2012 (77 FR 61786).

The last notification was filed with the Department on January 20, 2016. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on February 26, 2016 (81 FR 9884).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–11738 Filed 5–17–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Yoga Bridge Accreditation

Notice is hereby given that, on March 24, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Yoga Bridge Accreditation ("YBA") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the name and principal place of business of the standards development organization is: YBA (Yoga Bridge Accreditation), Portland, OR. The nature and scope of YBA's standards and development activities are: To set industry standards for a diverse research based yoga training & education. YBA works on two fronts: To certify individuals interested in yoga according to our Standards, and, to offer certified continuing education classes for professionals in non-yoga related fields to incorporate YBA teachings into their existing professions.

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–11740 Filed 5–17–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Members of SGIP 2.0, Inc.

Notice is hereby given that, on April 12, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Members of SGIP 2.0, Inc. ("MSGIP 2.0") have filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Machfu, Germantown, MD; OPC Foundation, Mantua, OH; Smarter Grid Solutions, Brooklyn, NY; Korea Electrotechnology Research Institute, Gyeongsangnam-do, REPUBLIC OF KOREA; Hitachi Consulting, Dallas, TX; and National Grid USA, Waltham, MA, have been added as parties to this venture.

Also, Hydro-Quebec, Montreal, CANADA; Valley View Corporation, Rockville, MD; Michigan Public Service Commission, Lansing, MI; WiMAX Forum, Portland, OR; Lakeview Consulting Group, Morgan Hill, CA; Buford Goff & Associates, Inc., Columbia, SC; Qualcomm Technologies, Inc., San Diego, CA; Z-Wave Alliance, Milpitas, CA; Wells Fargo, San Francisco, CA; Cetecom, Milpitas, CA; JKN Consulting, Scotts Valley, CA; Energy Central, Aurora, CO; and Jamaica Public Service Company Ltd., Kingston 5, JAMAICA, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and MSGIP 2.0 intends to file additional written notifications disclosing all changes in membership.

On February 5, 2013, MSGIP 2.0 filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on March 7, 2013 (78 FR 14836).

The last notification was filed with the Department on January 14, 2016. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on February 26, 2016 (81 FR 9883).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–11737 Filed 5–17–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On May 9, 2016, the Department of Justice lodged a proposed consent decree with the United States District Court for the District of Minnesota in the lawsuit entitled *United States and the State of Minnesota* v. *Southern Minnesota Beet Sugar Cooperative,* Civil Action No. 16–1205.

The United States and the State of Minnesota filed this lawsuit under the Clean Water Act. The complaint seeks injunctive relief and civil penalties for violations of Defendant's National Pollutant Discharge Elimination System ("NPDES") permit issued by the State to Southern Minnesota Beet Sugar Cooperative's sugar beet processing facility in Renville County, Minnesota. The consent decree requires the defendant to perform injunctive relief, pay a $1,000,000.00 civil penalty (split evenly between the United States and the State), and pay restitution to the State of $49,155.83.

The publication of this notice opens a period for public comment on the consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and the State of Minnesota* v. *Southern Minnesota Beet Sugar Cooperative,* D.J. Ref. No. 90–5–1–1–10696. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By e-mail	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the consent decree may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $17.00 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is $7.50.

Randall M. Stone,

Acting Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2016–11653 Filed 5–17–16; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Labor Organization and Auxiliary Reports

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Office of Labor Management Standards (OLMS) sponsored information collection request (ICR) revision titled, "Labor Organization and Auxiliary Reports," to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before June 17, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201604-1245-001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OLMS, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks approval under the PRA for revisions to the Labor Organization and Auxiliary Reports information collection. The Labor-Management Reporting and Disclosure Act requires a union to file an annual financial report and a copy of the union's constitution and bylaws with the DOL. Under certain circumstances, reports are required of a union officer and employee, employer, labor relations consultant, and surety company. Any such report is available for public disclosure. A filer is required to retain supporting records for five years; a union is also required to retain election records for one year. This information collection has been classified as a revision, because the OLMS is changing the instructions to the Form LM–3 and LM–4 Labor Organization Annual Reports, in order to mandate electronic filing, as well as amend the hardship exemption process for Form LM–2 filers. If approved, the changes for the Forms LM–2, LM–3, and LM–4 will apply to fiscal years beginning on or after January 1, 2017.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1245–0003. The current approval is scheduled to expire on March 31, 2019; however, the DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 20, 2016 (80 FR 42842).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1245–0003. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: DOL–OLMS.

Title of Collection: Labor Organization and Auxiliary Reports.

OMB Control Number: 1245–0003.

Affected Public: Private Sector—not-for-profit institutions.

Total Estimated Number of Respondents: 37,414.

Total Estimated Number of Responses: 37,414.

Total Estimated Annual Time Burden: 4,593,235 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: May 9, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–11695 Filed 5–17–16; 8:45 am]

BILLING CODE 4510–CP–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16–036)]

NASA Advisory Council; Science Committee; Planetary Protection Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Planetary Protection Subcommittee of the NASA Advisory Council (NAC). This Subcommittee reports to the Science Committee of the NAC. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Wednesday, June 1, 2016, 9:30 a.m. to 5:00 p.m., and Thursday, June 2, 2016, 8:45 a.m. to 3:30 p.m., Local Time.

ADDRESSES: NASA Headquarters, Room 1Q39, 300 E Street SW., Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. Ann Delo, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–0750, fax (202) 358–2779.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. The meeting will also be available telephonically and by WebEx. Any interested person may call the conference call number 1–888–324–3811 (USA toll free) or 1–210–234–8402, passcode 94125, to participate in this meeting by telephone. The WebEx link is *https://nasa.webex.com/*. The meeting number on June 1, 2016, is 995 907 813, passcode Protection_601. The meeting number on June 2, 2016, is 998 659 198, passcode Protection_602. The agenda for the meeting includes the following topics:

—Updates on Planetary Protection in the Mars Exploration Program

—Planetary Protection Technology Investments

Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID to Security before access to NASA Headquarters. Due to the Real ID Act, Public Law 109–13, any attendees with drivers licenses issued from non-compliant states/territories must present a second form of ID. [Federal employee badge; passport; active military identification card; enhanced driver's license; U.S. Coast Guard Merchant Mariner card; Native American tribal document; school identification accompanied by an item from LIST C (documents that establish employment authorization) from the "List of the Acceptable Documents" on Form I–9]. Non-compliant states/territories are: American Samoa, Illinois, Minnesota, Missouri, New Mexico and Washington. Foreign nationals attending this meeting will be required to provide a copy of their passport and visa in addition to providing the following information no less than 10 working days prior to the meeting: full name; gender; date/place of birth; citizenship; visa information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee; and home address to Ann Delo via email at *ann.b.delo@nasa.gov* or by fax at (202) 358–2779. U.S. citizens and Permanent Residents (green card holders) are requested to submit their name and affiliation 3 working days prior to the meeting to Ann Delo. It is imperative that this meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2016–11698 Filed 5–17–16; 8:45 am]

BILLING CODE 7510–13–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–025 and 52–026; NRC–2008–0252]

Vogtle Electric Generating Station, Units 3 and 4; Southern Nuclear Operating Company, Main Control Room Emergency Habitability System (VES) Design Changes

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption and combined license amendment; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is granting an exemption to allow a departure from the certification information of Tier 1 of the generic design control document (DCD) and is issuing License Amendment No. 48 to Combined Licenses (COLs), NPF–91 and NPF–92. The COLs were issued to Southern Nuclear Operating Company, Inc. (SNC); Georgia Power Company; Oglethorpe Power Corporation; MEAG Power SPVM, LLC; MEAG Power SPVJ, LLC; MEAG Power SPVP, LLC; Authority of Georgia; and the City of Dalton, Georgia (together "the licensee") for construction and operation of the Vogtle Electric Generating Plant (VEGP) Units 3 and 4, located in Burke County, Georgia.

The granting of the exemption allows the changes to Tier 1 information asked for in the amendment. Because the acceptability of the exemption was determined in part by the acceptability of the amendment, the exemption and amendment are being issued concurrently.

ADDRESSES: Please refer to Docket ID NRC–2008–0252 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0252. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "ADAMS Public Documents" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document. The request for the amendment and exemption was submitted by letter dated May 7, 2015, and it is available in ADAMS under Accession No. ML15127A469.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Paul Kallan, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2809, email: *Paul.Kallan@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is granting an exemption from paragraph B of Section III, "Scope and Contents," of appendix D, "Design Certification Rule for the AP1000," to part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), and is issuing License Amendment No. 48 to COLs NPF–91 and NPF–92, to the licensee. The exemption is required by paragraph A.4 of section VIII, "Processes for Changes and Departures," appendix D, to 10 CFR part 52 to allow the licensee to depart from Tier 1 information. With the requested amendment, the licensee sought proposed changes that would revise ASME safety classification and transition location, equipment orientation and removal, and identification of the number of emergency air storage tanks. The proposed changes to the Main Control Room Emergency Habitability System (VES) revises Tier 1 and corresponding information in COL Appendix C, Figure 2.2.5–1. It also revises Tier 2 information in the UFSAR.

Part of the justification for granting the exemption was provided by the review of the amendment. Because the exemption is necessary in order to issue the requested license amendment, the NRC granted the exemption and issued the amendment concurrently, rather than in sequence. This included issuing a combined safety evaluation containing the NRC staff's review of both the exemption request and the license amendment. The exemption met all applicable regulatory criteria set forth in 10 CFR 50.12, 10 CFR 52.7, and Section VIII.A.4 of appendix D to 10 CFR part 52. The license amendment was found to be acceptable as well. The combined safety evaluation is available in ADAMS under Accession No. ML16053A177.

Identical exemption documents (except for referenced unit numbers and license numbers) were issued to the licensee for VEGP Units 3 and 4 (COLs NPF–91 and NPF–92). The exemption documents for VEGP Units 3 and 4 can be found in ADAMS under Accession Nos. ML16053A133 and ML16053A136, respectively. The exemption is reproduced (with the exception of abbreviated titles and additional citations) in Section II of this document. The amendment documents for COLs NPF–91 and NPF–92 are available in ADAMS under Accession Nos. ML16053A146 and ML16053A148, respectively. A summary of the amendment documents is provided in Section III of this document.

II. Exemption

Reproduced below is the exemption document issued to Vogtle Units 3 and Unit 4. It makes reference to the combined safety evaluation that provides the reasoning for the findings made by the NRC (and listed under Item 1) in order to grant the exemption:

1. In a letter dated May 7, 2015, the licensee requested from the Commission an exemption from the provisions of 10 CFR part 52, appendix D, Section III.B, as part of license amendment request 15–006, "Main Control Room Emergency Habitability System (VES) Design Changes (LAR–15–006)."

For the reasons set forth in Section 3.1, "Evaluation of Exemption," of the NRC staff's Safety Evaluation, which can be found in ADAMS under Accession No. ML16053A177, the Commission finds that:

A. The exemption is authorized by law;

B. the exemption presents no undue risk to public health and safety;

C. the exemption is consistent with the common defense and security;

D. special circumstances are present in that the application of the rule in this circumstance is not necessary to serve the underlying purpose of the rule;

E. the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption; and

F. the exemption will not result in a significant decrease in the level of safety otherwise provided by the design.

2. Accordingly, the licensee is granted an exemption from the certified DCD Tier 1, as described in the licensee's request dated May 7, 2015. This exemption is related to, and necessary for the granting of License Amendment No. 48, which is being issued concurrently with this exemption.

3. As explained in Section 5.0, "Environmental Consideration," of the NRC staff's Safety Evaluation (ADAMS Accession No. ML16053A177), this exemption meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental

assessment needs to be prepared in connection with the issuance of the exemption.

4. This exemption is effective as of the date of its issuance.

III. License Amendment Request

By letter dated May 07, 2015, the licensee requested that the NRC amend the COLs for VEGP, Units 3 and 4, COLs NPF–91 and NPF–92. The proposed amendment is described in Section I of this **Federal Register** notice.

The Commission has determined for these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** on July 21, 2015 (80 FR 43123). No comments were received during the 30-day comment period.

The Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments.

IV. Conclusion

Using the reasons set forth in the combined safety evaluation, the staff granted the exemption and issued the amendment that the licensee requested on May 7, 2015. The exemption and amendment were issued on March 30, 2016 as part of a combined package to the licensee (ADAMS Accession No. ML16053A091).

Dated at Rockville, Maryland, this 11th day of May 2016.

For the Nuclear Regulatory Commission.

John McKirgan,

Acting Chief, Licensing Branch 4, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2016–11733 Filed 5–17–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–017; NRC–2008–0066]

Dominion Virginia Power; North Anna, Unit 3

AGENCY: Nuclear Regulatory Commission.

ACTION: Combined license application; receipt.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is giving notice once each week for four consecutive weeks of the North Anna Unit 3 combined license (COL) application from Dominion Virginia Power (Dominion).

DATES: May 18, 2016.

ADDRESSES: Please refer to Docket ID NRC–2008–0066 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0066. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: James Shea, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1388, email: *James.Shea@nrc.gov.*

SUPPLEMENTARY INFORMATION: The Virginia Electric and Power Company, doing business as Dominion Virginia Power (Applicant) has filed an application for a COL with the NRC under Section 103 of the Atomic Energy Act of 1954, as amended, and part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), "Licenses, Certifications, and Approvals for Nuclear Power Plants." Through the Application, which is currently under review by the NRC staff, the Applicant seeks to construct and operate an Economic Simplified Boiling-Water Reactor at the North Anna Power Station, which is located in Louisa County, Virginia. An applicant may seek a COL in accordance with subpart C of 10 CFR part 52. The information submitted by the applicant includes certain administrative information, such as financial qualifications submitted pursuant to 10 CFR 52.77, as well as technical information submitted pursuant to 10 CFR 52.79. These notices are being provided in accordance with the requirements in 10 CFR 50.43(a)(3).

Dated at Rockville, Maryland, this 11th day of May, 2016.

For the Nuclear Regulatory Commission.

Ronaldo Jenkins,

Chief, Licensing Branch 3, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2016–11750 Filed 5–17–16; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service; January 2016

AGENCY: U.S. Office of Personnel Management (OPM).

ACTION: Notice.

SUMMARY: This notice identifies Schedule A, B, and C appointing authorities applicable to a single agency that were established or revoked from January 1, 2016, to January 31, 2016.

FOR FURTHER INFORMATION CONTACT: Senior Executive Resources Services, Senior Executive Services and Performance Management, Employee Services, 202–606–2246.

SUPPLEMENTARY INFORMATION: In accordance with 5 CFR 213.103, Schedule A, B, and C appointing authorities available for use by all agencies are codified in the Code of Federal Regulations (CFR). Schedule A, B, and C appointing authorities applicable to a single agency are not codified in the CFR, but the Office of Personnel Management (OPM) publishes a notice of agency-specific authorities established or revoked each month in the **Federal Register** at *www.gpo.gov/fdsys/.* OPM also publishes an annual notice of the consolidated listing of all Schedule A, B, and C appointing authorities, current as of June 30, in the **Federal Register**.

Schedule A

No Schedule A Authorities to report during January 2016.

Schedule B

No Schedule B Authorities to report during January 2016.

Schedule C

The following Schedule C appointing authorities were approved during January 2016.

Agency name	Organization name	Position title	Authorization number	Effective date
Department of Agriculture	Office of Civil Rights	Special Advisor	DA160029	1/5/2016
	Office of the Secretary	Special Assistant	DA160031	1/6/2016
		Senior Advisor	DA160032	1/6/2016
	Farm Service Agency	State Executive Director—New Hampshire.	DA160033	1/6/2016
	Office of the Under Secretary for Marketing and Regulatory Programs.	Confidential Assistant	DA160035	1/19/2016
Department of Commerce	Office of Assistant Secretary for Industry and Analysis.	Deputy Director, Office of Advisory Committees and Industry Outreach.	DC160053	1/4/2016
	Office of Public Affairs	Chief Speechwriter and Advisor	DC160054	1/4/2016
	Office of the Secretary	Director, Office of Faith Based and Neighborhood Partnerships.	DC160034	1/13/2016
	Office of Assistant Secretary for Enforcement and Compliance.	Special Assistant	DC160075	1/15/2016
Department of Defense	Office of the Assistant Secretary of Defense (Special Operations/Low Intensity Conflict and Interdependent Capabilities).	Special Assistant for Special Operations/Low Intensity Conflict.	DD160054	1/14/2016
	Office of the Assistant Secretary of Defense (International Security Affairs).	Special Assistant for Russia, Ukraine and Eurasia.	DD160060	1/15/2016
	Office of the Assistant Secretary of Defense (International Security Affairs).	Special Assistant	DD160057	1/20/2016
	Office of the Secretary of Defense	Advance Officer	DD160047	1/28/2016
Department of Education	Office of Elementary and Secondary Education.	Strategic Communications Manager.	DB160020	1/8/2016
	Office of the Secretary	Director of Scheduling and Advance.	DB160021	1/8/2016
	Office of the Under Secretary	Director of College Scorecard	DB160023	1/21/2016
	Office of Communications and Outreach.	Deputy Chief of Staff	DB160024	1/21/2016
		Confidential Assistant	DB160027	1/21/2016
		Deputy Assistant Secretary for State and Local Engagement.	DB160028	1/21/2016
		Senior Advisor	DB160029	1/21/2016
	Office of Postsecondary Education	Senior Policy Advisor	DB160025	1/21/2016
Department of Energy	Office of the Under Secretary	Special Assistant	DE160048	1/8/2016
	Office of the Secretary	Deputy White House Liaison and Special Project Manager.	DE160050	1/8/2016
		Special Assistant	DE160051	1/19/2016
	Office of Scheduling and Advance	Special Assistant	DE160046	1/19/2016
	Office of Assistant Secretary for Congressional and Intergovernmental Affairs.	Advisor for Intergovernmental and External Affairs.	DE160047	1/21/2016
Environmental Protection Agency	Office of Public Affairs	Deputy Director of Speechwriting	EP160019	1/20/2016
Export-Import Bank	Office of Communications	Director of Speechwriter	EB160002	1/15/2016
Department of Health and Human Services.	Office of the Assistant Secretary for Public Affairs.	Director of Communications, Public Health.	DH160048	1/4/2016
	Office of the Secretary	Policy Advisor	DH160039	1/6/2016
		Deputy White House Liaison	DH160046	1/6/2016
		White House Liaison for Political Personnel, Boards and Commissions.	DH160045	1/7/2016
		Senior Advisor	DH160041	1/11/2016
	Office of the Assistant Secretary for Legislation.	Policy Advisor	DH160040	1/6/2016
	Office of the Assistant Secretary for Children and Families.	Special Assistant	DH160042	1/6/2016
	Office of the Deputy Secretary	Chief of Staff	DH160043	1/6/2016
Department of Homeland Security	Office of the Executive Secretariat	Deputy Secretary Briefing Book Coordinator.	DM160101	1/19/2016

Agency name	Organization name	Position title	Authorization number	Effective date
		Secretary's Briefing Book Coordinator.	DM160104	1/19/2016
		Congressional Correspondence Analyst.	DM160109	1/21/2016
		Special Assistant	DM160108	1/28/2016
	Federal Emergency Management Agency.	Counselor	DM160105	1/20/2016
	Office of Assistant Secretary for Legislative Affairs.	Director of Legislative Affairs	DM160110	1/20/2016
	Ombudsman, Citizenship and Immigration Services.	Special Advisor for Public Engagement.	DM160106	1/28/2016
Department of Housing and Urban Development.	Office of the Administration	Advance Coordinator	DU160005	1/11/2016
	Office of Housing	Special Assistant	DU160007	1/21/2016
Department of the Interior	Office of Assistant Secretary—Fish and Wildlife and Parks.	Advisor	DI160028	1/16/2016
	Secretary's Immediate Office	Advisor	DI160026	1/21/2016
Department of Justice	Office of the Associate Attorney General.	Deputy Chief of Staff and Senior Counsel.	DJ160032	1/6/2016
	Office of the Attorney General	Director of Scheduling	DJ160041	1/14/2016
		Special Assistant	DJ160049	1/29/2016
	Office on Violence Against Women.	Advisor	DJ160043	1/19/2016
	Office of Justice Programs	Senior Policy Advisor	DJ160044	1/21/2016
Department of Labor	Office of the Secretary	White House Liaison and Counselor.	DL160018	1/5/2016
	Office of the Deputy Secretary	Special Assistant	DL160027	1/13/2016
	Office of the Assistant Secretary for Policy.	Senior Policy Advisor	DL160029	1/20/2016
	Office of Public Affairs	Director of Digital Strategy	DL160030	1/20/2016
	Mine Safety and Health Administration.	Chief of Staff	DL160033	1/29/2016
Office of Management and Budget	General Government Programs	Confidential Assistant	BO160013	1/7/2016
	Office of the Director	Confidential Assistant	BO160015	1/12/2016
Office of Personnel Management	Office of the Director	Senior Advisor	PM160014	1/7/2016
Small Business Administration	Office of Field Operations	Regional Administrator, Region VIII, Denver, Colorado.	SB160008	1/13/2016
Social Security Administration	Office of the Commissioner	Senior Advisor	SZ160006	1/5/2016
Department Of State	Bureau of Arms Control, Verification, and Compliance.	Public Affairs Specialist	DS160023	1/6/2016
	Bureau for Education and Cultural Affairs.	Deputy Assistant Secretary	DS160015	1/7/2016
	Foreign Policy Planning Staff	Foreign Affairs Officer	DS160024	1/13/2016
	Office of the Chief of Protocol	Protocol Officer (Ceremonials)	DS160021	1/19/2016
Department of Transportation	Civil Rights	Special Assistant	DT160025	1/28/2016
Department of the Treasury	Office of Assistant Secretary (Legislative Affairs).	Special Assistant	DY160022	1/11/2016
	Office of the Secretary of the Treasury.	Special Assistant	DY160024	1/19/2016
	Office of the Assistant Secretary for Management.	Special Assistant	DY160030	1/21/2016
United States International Trade Commission.	Office of Commissioner Pinkert	Confidential Assistant	TC160003	1/14/2016

The following Schedule C appointing authorities were revoked during January 2016.

Agency name	Organization name	Position title	Request number	Date vacated
Department of Agriculture	Rural Housing Service	State Director	DA120064	01/06/2016
	Office of the Secretary	Deputy White House Liaison	DA150147	01/13/2016
	Office of Communications	Senior Advisor for Strategic Communications.	DA150151	01/15/2016
	Farm Service Agency	State Executive Director (Wisconsin).	DA130186	01/23/2016
Department of Commerce	Office of Public Affairs	Deputy Speechwriter	DC150153	01/09/2016
	Office of Legislative and Intergovernmental Affairs.	Associate Director of Legislative Affairs and Senior Advisor for Native American Affairs.	DC150064	01/15/2016

Agency name	Organization name	Position title	Request number	Date vacated
	Economic Development Administration.	Senior Advisor	DC140150	01/23/2016
	Office of the Chief of Staff	Senior Protocol Officer	DC140122	01/23/2016
Office of the Secretary of Defense	Office of the Secretary	Special Assistant to the Secretary of Defense.	DD150150	01/03/2016
	Office of Principal Deputy Under Secretary for Policy.	Special Assistant to the Deputy Under Secretary of Defense for Strategy, Plans and Forces.	DD150134	01/08/2016
	Office of the Secretary	Confidential Assistant to the Secretary of Defense.	DD070181	01/09/2016
	Office of the Assistant Secretary of Defense (International Security Affairs).	Special Assistant to the Deputy Assistant Secretary of Defense, Russia, Ukraine and Eurasia.	DD150036	01/16/2016
Department of the Air Force	Office of the Under Secretary	Special Assistant	DF150024	01/29/2016
Department of Education	Office of Communications and Outreach.	Confidential Assistant (2)	DB150026	01/09/2016
			DB140040	01/23/2016
		Deputy Chief of Staff	DB150117	01/23/2016
	Office of the Secretary	Special Assistant	DB150043	01/09/2016
		Deputy Director, Office of Educational Technology	DB140012	01/23/2016
	Office of the Under Secretary	Deputy Director of the White House Initiative on American Indian and Alaska Native Education.	DB120072	01/09/2016
		Deputy Director (White House Initiative on Educational Excellence for African Americans).	DB150027	01/30/2016
	Office of Postsecondary Education	Deputy Chief of Staff	DB150096	01/23/2016
	Office of Elementary and Secondary Education.	Chief of Staff	DB140049	01/29/2016
Department of Energy	Office of Management	Special Assistant	DE140054	01/09/2016
	Office of the Secretary	Deputy White House Liaison	DE140061	01/09/2016
	Office of the Under Secretary for Science.	Senior Advisor	DE140057	01/09/2016
Environmental Protection Agency	Office of Advance Staff	Deputy for Advance	EP150007	01/16/2016
	Office of the Associate Administrator for Congressional and Intergovernmental Relations.	Deputy Associate Administrator for Congressional Affairs.	EP130031	01/16/2016
	Office of Public Affairs	Speech Writer	EP140031	01/23/2016
General Services Administration	Office of Communications and Marketing.	Press Secretary	GS150034	01/03/2016
Department of Health and Human Services.	Office of the Assistant Secretary for Public Affairs.	Communications Director for Public Health.	DH150019	01/03/2016
	Office of Intergovernmental and External Affairs.	Director of Business Outreach	DH140073	01/08/2016
	Office of the Secretary	White House Liaison for Political Personnel, Boards and Commissions.	DH130091	01/08/2016
		Deputy White House Liaison	DH140002	01/09/2016
		Director of Scheduling and Advance	DH140119	01/09/2016
		Special Assistant	DH140139	01/09/2016
	Office of the Assistant Secretary for Children and Families.	Confidential Assistant	DH150003	01/09/2016
	Office of the Assistant Secretary for Legislation.	Special Assistant for Human Services.	DH140126	01/09/2016
	Office of the Deputy Secretary	Chief of Staff to the Deputy Secretary.	DH120045	01/09/2016
	Office of the Assistant Secretary for Public Affairs.	Confidential Assistant	DH150178	01/29/2016
Department of Homeland Security	Office of Assistant Secretary for Legislative Affairs.	Legislative Affairs Specialist	DM160035	01/08/2016
	Office of the Under Secretary for National Protection and Programs Directorate.	Advisor for Counterterrorism and Intelligence.	DM140246	01/10/2016
		Confidential Assistant	DM140218	01/10/2016
	Federal Emergency Management Agency.	Special Assistant to the Administrator.	DM140112	01/23/2016
	Office of the Executive Secretariat	Writer-Editor	DM140232	01/23/2016
Department of the Interior	Office of Assistant Secretary (Water and Science).	Counselor to the Assistant Secretary (Water and Science).	DI140040	01/09/2016

Agency name	Organization name	Position title	Request number	Date vacated
	Office of Assistant Secretary (Fish, Wildlife, and Parks).	Advisor	DI140073	01/15/2016
	Secretary's Immediate Office	Special Assistant	DI140072	01/23/2016
Department of Justice	Office of Justice Programs	Director, Faith-Based and Neighborhood Partnerships.	DJ110002	01/09/2016
		Policy Advisor	DJ140117	01/23/2016
		Senior Counsel	DJ150084	01/30/2016
	Office of Legislative Affairs	Attorney Advisor	DJ150080	01/09/2016
	Office of the Associate Attorney General.	Deputy Chief of Staff and Counsel	DJ150002	01/09/2016
	Office of the Attorney General	Special Assistant	DJ150020	01/23/2016
		Special Assistant and Scheduler	DJ150082	01/23/2016
Department of Labor	Office of the Assistant Secretary for Policy.	Associate Deputy Assistant Secretary.	DL150004	01/02/2016
		Senior Policy Advisor	DL140081	01/09/2016
	Office of the Secretary	Special Assistant	DL150015	01/09/2016
		White House Liaison	DL140037	01/10/2016
	Mine Safety and Health Administration.	Chief of Staff	DL140100	01/23/2016
	Office of the Deputy Secretary	Special Assistant	DL150024	01/23/2016
	Office of the Secretary	Special Assistant	DL140048	01/23/2016
National Endowment for the Humanities.	Office of the Chairman	Confidential Assistant to the Chief of Staff.	NH140005	01/23/2016
Office of Management and Budget	Office of the Director	Assistant to the Deputy Director for Management.	BO150030	01/02/2016
	Office of Federal Procurement Policy.	Confidential Assistant	BO150041	01/23/2016
Small Business Administration	Office of Faith-Based and Community Initiatives.	Assistant Administrator for Public Engagement.	SB150036	01/19/2016
	Office of the Administrator	Director of Scheduling and Advance.	SB140035	01/22/2016
		Special Assistant for Scheduling and Advance	SB150027	01/24/2016
	Office of Intergovernmental Affairs	Associate Administrator for Intergovernmental Affairs.	SB150037	01/23/2016
Department of State	Office of the Deputy Secretary for Management and Resources.	Senior Advisor	DS140077	01/09/2016
	Office of the Global Women's Issues.	Senior Advisor	DS130098	01/18/2016
	Bureau of Arms Control, Verification, and Compliance.	Public Affairs Specialist	DS150015	01/23/2016
Department of Transportation	Office of General Counsel	Associate General Counsel	DT140057	01/09/2016
Department of the Treasury	Office of the Secretary of the Treasury.	Special Assistant	DY140114	01/09/2016
United States International Trade Commission.	Office of Commissioner Pinkert	Executive Assistant	TC120009	01/04/2016
	Office of Commissioner Schmidtlein.	Confidential Assistant	TC140010	01/22/2016
Department of Veterans Affairs	Office of the Assistant Secretary for Public and Intergovernmental Affairs.	Special Assistant	DV130025	01/22/2016

Authority: 5 U.S.C. 3301 and 3302; E.O. 10577, 3 CFR, 1954–1958 Comp., p. 218.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

[FR Doc. 2016–11723 Filed 5–17–16; 8:45 am]

BILLING CODE 6325–39–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0237, Information and Instructions on Your Reconsideration Rights, RI 38–47

AGENCY: U.S. Office of Personnel Management.

ACTION: 60-Day Notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a revised information collection request (ICR) 3206–0237, Information and Instruction on Your Reconsideration Rights, RI 38–47. As required by the Paperwork Reduction Act of 1995 (Public Law 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. Law 104–106), OPM is soliciting comments for this collection.

DATES: Comments are encouraged and will be accepted until July 18, 2016. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to Retirement Services, U.S. Office of Personnel Management, 1900 E Street NW., Washington, DC 20415, Attention: Alberta Butler, Room 2347–E or sent by email to *Alberta.Butler@opm.gov.*

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of

Personnel Management, 1900 E Street NW., Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent by email to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910.

SUPPLEMENTARY INFORMATION:

The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of OPM, including whether the information will have practical utility;
2. Evaluate the accuracy of OPM's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

RI 38–47 outlines the procedures required to request reconsideration of an initial OPM decision about Civil Service or Federal Employees retirement, Federal or Retired Federal Employees Health Benefits requests to enroll or change enrollment or Federal Employees' Group Life Insurance coverage. This form lists the procedures and time periods required for requesting reconsideration.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Information and Instruction on Your Reconsideration Rights.

OMB: 3206–0237.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 3,100.

Estimated Time per Respondent: 45 minutes.

Total Burden Hours: 2325 hours.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

[FR Doc. 2016–11720 Filed 5–17–16; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service; February 2016

AGENCY: U.S. Office of Personnel Management (OPM).

ACTION: Notice.

SUMMARY: This notice identifies Schedule A, B, and C appointing authorities applicable to a single agency that were established or revoked from February 1, 2016, to February 29, 2016.

FOR FURTHER INFORMATION CONTACT: Senior Executive Resources Services, Senior Executive Services and Performance Management, Employee Services, 202–606–2246.

SUPPLEMENTARY INFORMATION: In accordance with 5 CFR 213.103, Schedule A, B, and C appointing authorities available for use by all agencies are codified in the Code of Federal Regulations (CFR). Schedule A, B, and C appointing authorities applicable to a single agency are not codified in the CFR, but the Office of Personnel Management (OPM) publishes a notice of agency-specific authorities established or revoked each month in the **Federal Register** at *www.gpo.gov/fdsys/.* OPM also publishes an annual notice of the consolidated listing of all Schedule A, B, and C appointing authorities, current as of June 30, in the **Federal Register.**

Schedule A

No Schedule A Authorities to report during February 2016.

Schedule B

Section 213.3250 Consumer Financial Protection Bureau (Sch. B)

One position of Deputy Director; and one position of Associate Director of the Division of Supervision, Enforcement, and Fair Lending.

Schedule C

The following Schedule C appointing authorities were approved during February 2016.

Agency name	Organization name	Position title	Authorization No.	Effective date
Department of Agriculture	Rural Housing Service	State Director	DA160067	2/5/2016
Department of Commerce	Office of the Chief of Staff	Scheduling Assistant	DC160083	2/2/2016
Commodity Futures Trading Commission.	Office of the Chairperson	Special Advisor	CT160001	2/3/2016
Department of Defense	Office of the Under Secretary of Defense (Policy).	Special Assistant for Deputy Assistant Secretary of Defense for Plans.	DD160064	2/4/2016
	Office of the Assistant Secretary of Defense (Global Strategic Affairs).	Special Assistant, Plans and Capabilities.	DD160033	2/10/2016
Department of Education	Office of the Secretary	Director of Advance	DB160031	2/3/2016
		Deputy Director, Education Technology.	DB160033	2/3/2016
	Office of the Under Secretary	Policy Advisor	DB160022	2/10/2016
Department of Energy	Office of the Deputy Secretary	Special Assistant	DE160038	2/10/2016
	Office of the Secretary of Energy Advisory Board.	Deputy Press Secretary	DE160059	2/10/2016
	Office of Public Affairs	Chief Speechwriter	DE160060	2/10/2016
Environmental Protection Agency	Office of the Associate Administrator for Congressional and Intergovernmental Relations.	Deputy Associate Administrator for Congressional Affairs.	EP160020	2/12/2016
	Office of Information Analysis and Access.	Data Analyst	EP160023	2/12/2016
Department of Homeland Security	Office of Assistant Secretary for Legislative Affairs.	Intergovernmental Affairs Coordinator.	DM160124	2/5/2016
Department of Housing and Urban Development.	Office of Congressional and Intergovernmental Relations.	Advisor	DU160009	2/2/2016
Department of the Interior	Secretary's Immediate Office	Special Assistant	DI160027	2/2/2016

Agency name	Organization name	Position title	Authorization No.	Effective date
Department of Justice	Office of Legislative Affairs	Attorney Advisor	DJ160052	2/10/2016
	Office on Violence Against Women.	Senior Advisor	DJ160053	2/17/2016
	Office of Public Affairs	Chief Speechwriter	DJ160054	2/18/2016
	Office of Justice Programs	Director, Center for Faith-Based and Neighborhood Partnerships.	DJ160056	2/25/2016
Department of Labor	Office of Disability Employment Policy.	Senior Advisor	DL160032	2/5/2016
	Occupational Safety and Health Administration.	Senior Advisor	DL160034	2/11/2016
Office of Personnel Management	Healthcare and Insurance	Program Analyst	PM160015	2/17/2016
Office of the United States Trade Representative.	Intergovernmental Affairs and Public Liaison.	Director for Private Sector Engagement.	TN160004	2/5/2016
Small Business Administration	Office of Communications and Public Liaison.	Senior Advisor for Strategic Communications.	SB160011	2/5/2016
		Deputy Associate Administrator for Communications and Public Liaison.	SB160013	2/5/2016
Department of State	Office of the Secretary	Program Analyst	DS160045	2/5/2016
		Senior Advisor	DS150108	2/29/2016
Department of the Treasury	Office of Assistant Secretary for Management.	Confidential Assistant	DY160034	2/2/2016
		Special Advisor	DY160035	2/2/2016
	United States Mint	Senior Advisor	DY160036	2/2/2016
	Office of Secretary of the Treasury	Deputy White House Liaison	DY160041	2/5/2016
	Office of Under Secretary for Domestic Finance.	Outreach Manager	DY160040	2/10/2016

The following Schedule C appointing authorities were revoked during February 2016.

Agency name	Organization name	Position title	Request number	Vacate date
Department of Commerce	Office of Business Liaison	Senior Advisor	DC140011	02/05/2016
	Office of Legislative and Intergovernmental Affairs.	Special Assistant	DC150138	02/05/2016
Office of the Secretary Of Defense	Office of Principal Deputy Under Secretary for Policy.	Special Assistant to Deputy Assistant Secretary of Defense, Plans.	DD140125	02/06/2016
	Office of the Secretary	Advance Officer	DD130123	02/06/2016
		Special Advisor to the Secretary of Defense.	DD130116	02/07/2016
	Office of the Assistant Secretary of Defense (Global Strategic Affairs).	Special Assistant to the Deputy Under Secretary of Defense for Strategy, Plans and Forces.	DD150013	02/09/2016
Department of Education	Office of Communications and Outreach.	Assistant Press Secretary	DB140053	02/12/2016
Environmental Protection Agency	Office of the Administrator	Special Assistant to the Chief of Staff.	EP150006	02/06/2016
	Office of Public Affairs	Advisor for Digital Strategy and Engagement.	EP140047	02/20/2016
Federal Maritime Commission	Federal Maritime Commission	Senior Legislative and Public Affairs Specialist.	MC160001	02/05/2016
Department of Health and Human Services.	Office of the Assistant Secretary for Public Affairs.	Senior Advisor	DH150163	02/05/2016
		Special Assistant for Specialty Media.	DH140060	02/19/2016
	Office of Communications	Senior Advisor	DH150039	02/12/2016
Department of Homeland Security	Ombudsman, Citizenship and Immigration Services.	Public Affairs Specialist	DM150013	02/01/2016
	Office of the Under Secretary for Science and Technology.	Special Assistant to the Under Secretary for Science and Technology.	DM150064	02/02/2016
	Office of Assistant Secretary for Legislative Affairs.	Director of Legislative Affairs for Intelligence and Analysis.	DM100222	02/06/2016
	Office of the Assistant Secretary for Public Affairs.	Assistant Press Secretary	DM150221	02/20/2016
Department of Housing and Urban Development.	Office of Housing	Public Affairs Specialist	DU130013	02/23/2016
	Office of Public Affairs	Deputy Press Secretary	DU110030	02/26/2016

Agency name	Organization name	Position title	Request number	Vacate date
Department of Labor	Office of the Deputy Secretary	Senior Policy Advisor	DL150059	02/20/2016
Office of Personnel Management	Office of the Director	Assistant Director, Office of Public Engagement.	PM140028	02/20/2016
Small Business Administration	Office of Communications and Public Liaison.	Deputy Assistant Administrator for Communications and Public Liaison.	SB150008	02/06/2016
		Speechwriter	SB150038	02/06/2016
	Office of the Administrator	Senior Advisor to the Administrator.	SB150055	02/20/2016
Department of State	Office of the Secretary	Special Assistant	DS130052	02/28/2016
Department of Transportation	Office of the Secretary	Special Assistant to the Secretary	DT150007	02/08/2016
	Office of Assistant Secretary for Governmental Affairs.	Special Assistant	DT140049	02/20/2016

Authority: 5 U.S.C. 3301 and 3302; E.O. 10577, 3 CFR, 1954–1958 Comp., p. 218.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

[FR Doc. 2016–11724 Filed 5–17–16; 8:45 am]

BILLING CODE 6325–39–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77821; File No. SR–ISE–2016–13]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees

May 12, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 2, 2016, the International Securities Exchange, LLC (the "Exchange" or the "ISE") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change, as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The ISE proposes to eliminate Priority Customer complex order rebates for certain "net zero" complex orders. The text of the proposed rule change is available on the Exchange's Web site (*http://www.ise.com*), at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange provides rebates to Priority Customer[3] complex orders that trade with non-Priority Customer complex orders in the complex order book or trade with quotes and orders on the regular order book. Rebates are tiered based on a member's average daily volume ("ADV") executed during a given month as follows: 0 to 29,999 contracts ("Tier 1"), 30,000 to 59,999 contracts ("Tier 2"), 60,000 to 99,999 contracts ("Tier 3"), 100,000 to 149,999 ("Tier 4"), 150,000 to 199,999 contracts ("Tier 5"), and 200,000 or more contracts ("Tier 6"). In Select Symbols the rebate is $0.30 per contract for Tier 1, $0.35 per contract for Tier 2, $0.41 per contract for Tier 3, $0.44 per contract for Tier 4, $0.46 per contract for Tier 5, and $0.47 per contract for Tier 6. In Non-Select Symbols the rebate is $0.63 per contract for Tier 1, $0.71 per contract for Tier 2, $0.79 per contract for Tier 3, $0.81 per contract for Tier 4, $0.83 per contract for Tier 5, and $0.84 per contract for Tier 6.

Recently, a market participant has been entering a large volume of valueless complex orders that trade at a net price at or near $0.00 (*i.e.,* "net zero" complex orders) with the sole intention of earning a rebate.[4] While these complex orders would generally not find a counterparty in the complex order book, they may leg in to the regular order book where they are typically executed by Market Makers[5] on the individual legs. The fee that Market Makers quoting in Select Symbols pay when a complex order legs into their quote is substantially higher than their fee or rebate for regular orders that trade against their quotes. In particular, a Market Maker providing liquidity on the individual leg would typically pay a maker fee of only $0.10 per contract,[6] or in the case of Market Makers that achieve Market Maker Plus status,[7] would earn a maker rebate ranging from $0.10 per contract to $0.22 per contract. When trading against a Priority Customer complex order that legs in from the complex order book, however, that same Market Maker is charged a maker fee of $0.30 per contract.[8] In Non-Select Symbols, Market Makers pay a fee of $0.25 per contract subject to certain tier discounts,[9] or $0.20 per contract for orders sent by an Electronic Access Member.[10]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A "Priority Customer" is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in ISE Rule 100(a)(37A).

[4] For example, a market participant could enter a "net zero" complex order that buys 500 contracts of the $193 March 6, 2016 SPY Put at a price of $0.03 and sells 500 contracts of the $193.50 March 6, 2016 SPY Put at a price of $0.03 for a net price of $0.00.

[5] The term "Market Makers" refers to "Competitive Market Makers" and "Primary Market Makers" collectively. See ISE Rule 100(a)(25).

[6] This maker fee also applies to Non-ISE Market Maker, Firm Proprietary/Broker Dealer and Professional Customer orders in Select Symbols. Priority Customer orders are not charged a maker fee in Select Symbols for orders entered on the regular order book.

A "Non-ISE Market Maker" is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended, registered in the same options class on another options exchange.

A "Firm Proprietary" order is an order submitted by a member for its own proprietary account.

A "Broker-Dealer" order is an order submitted by a member for a broker-dealer account that is not its own proprietary account.

A "Professional Customer" is a person or entity that is not a broker/dealer and is not a Priority Customer.

[7] A Market Maker Plus is a Market Maker who is on the National Best Bid or National Best Offer a

By entering essentially valueless complex orders, this market participant or others employing the same strategy are able to recover rebates for essentially non-economic trades at the expense of the Exchange and the market participants on the other side of the trade. This behavior is a form of rebate arbitrage, and the Exchange believes that it is in the best interest of the Exchange and its members to remove the incentives that promote this activity. The Exchange therefore proposes to eliminate Priority Customer rebates for "net zero" complex orders that are entered on behalf of originating market participants that execute an ADV of at least 10,000 "net zero" complex orders in a given month. For purposes of determining which complex orders qualify as "net zero" the Exchange will count all complex orders that leg in to the regular order book and are executed at a net price that is within a range of $0.01 credit and $0.01 debit.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[11] in general, and Section 6(b)(4) of the Act,[12] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities.

The Exchange believes that the proposed fee change is reasonable and equitable as it is designed to remove financial incentives for market participants to engage in rebate arbitrage by entering "net zero" complex orders on the Exchange that do not have any economic substance. As explained above, Priority Customer complex orders, including "net zero" complex orders that leg in to the regular order book, are currently paid significant rebates by the Exchange, which are funded in part by charging higher fees to the market participants that trade against these orders. The Exchange believes that eliminating the rebate provided to "net zero" complex orders will discourage market participants from entering these valueless orders, which are entered for the sole purpose of earning a rebate. The Exchange also believes that the proposed rule change is not unfairly discriminatory as it is designed to stop market participants from taking advantage of Exchange rebates by entering orders that lack economic substance. The Exchange is proposing to eliminate Priority Customer complex order rebates for all market participants that enter a large number of "net zero" complex orders. To the extent that those market participants enter legitimate complex orders, however, they will continue to receive the same rebates that they do today. In addition, market participants that enter an insubstantial volume of "net zero" complex orders will also continue to receive rebates. The Exchange does not believe that it is unfairly discriminatory to continue to offer rebates to firms that do not hit the proposed "net zero" ADV threshold as this more limited trading activity is not indicative of rebate arbitrage.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[13] the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is designed to eliminate the ability for certain market participants to engage in rebate arbitrage to the detriment of the Exchange and its members. The Exchange operates in a highly competitive market in which market participants can readily direct their order flow to competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and rebates to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed fee changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act[14] and subparagraph (f)(2) of Rule 19b–4 thereunder,[15] because it establishes a due, fee, or other charge imposed by ISE.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–ISE–2016–13 on the subject line.

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specified percentage of the time for series trading between $0.03 and $3.00 (for options whose underlying stock's previous trading day's last sale price was less than or equal to $100) and between $0.10 and $3.00 (for options whose underlying stock's previous trading day's last sale price was greater than $100) in premium in each of the front two expiration months. The specified percentage is at least 80% but lower than 85% of the time for Tier 1, at least 85% but lower than 95% of the time for Tier 2, and at least 95% of the time for Tier 3. A Market Maker's single best and single worst quoting days each month based on the front two expiration months, on a per symbol basis, will be excluded in calculating whether a Market Maker qualifies for this rebate, if doing so will qualify a Market Maker for the rebate.

[8] This higher maker fee for trading against a Priority Customer complex order that legs in to the regular order book also applies to Non-ISE Market Maker orders.

[9] *See* Schedule of Fees, Section IV.C.

[10] There is no fee difference in Non-Select Symbols for trading against Priority Customer complex orders that leg in to the regular order book. Non-ISE Market Maker, Firm Proprietary/Broker-Dealer and Professional Customer orders in Non-Select Symbols are charged a fee of $0.72 per contract. Priority Customer orders are not charged a fee in Non-Select symbols for orders entered on the regular order book.

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78f(b)(8).

[14] 15 U.S.C. 78s(b)(3)(A)(ii).

[15] 17 CFR 240.19b–4(f)(2).

Paper Comments

- Send paper comments in triplicate to Elizabeth Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2016–13. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the ISE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2016–13 and should be submitted by June 8, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–11644 Filed 5–17–16; 8:45 am]

BILLING CODE 8011–01–P

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[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77820; File No. SR–NYSEArca–2016–44]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change Amending NYSE Arca Equities Rule 7.31P(h) To Add a New Discretionary Pegged Order

May 12, 2016.

On March 11, 2016, NYSE Arca, Inc. ("Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Exchange Rule 7.31P(h) to add a new Discretionary Pegged Order. The proposed rule change was published for comment in the **Federal Register** on March 30, 2016.[3] The Commission received two comment letters on the proposed rule change,[4] as well as a response from the Exchange.[5]

Section 19(b)(2) of the Act[6] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is May 14, 2016. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[7] designates June 28, 2016, as the date by which the Commission should either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File Number SR–NYSEArca–2016–44).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–11643 Filed 5–17–16; 8:45 am]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 77441 (March 24, 2016), 81 FR 17749.

[4] *See* Letter from Sophia Lee, General Counsel, IEX Group, Inc., to Brent J. Fields, Secretary, Commission, dated April 15, 2016; Letter from John C. Nagel, Managing Director and Senior Deputy General Counsel, Citadel LLC, to Brent J. Fields, Secretary, Commission, dated April 20, 2016.

[5] *See* Letter from Elizabeth K. King, General Counsel and Corporate Secretary, New York Stock Exchange, to Brent J. Fields, Secretary, Commission, dated April 27, 2016.

[6] 15 U.S.C. 78s(b)(2).

[7] 15 U.S.C. 78s(b)(2).

[8] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77819; File No. SR–BatsEDGX–2016–17]

Self-Regulatory Organizations; Bats EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Description of Price Improving Orders Under Subparagraph (6) to Rule 21.1(d) and Add Subparagraph (4) to Rule 21.1(h) Modifying the Operation of Orders Subject to the Display Price Sliding Process When a Contra-Side Post Only Order Is Received by the Bats EDGX Exchange Options Platform

May 12, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 3, 2016, Bats EDGX Exchange, Inc. f/k/a EDGX Exchange, Inc. (the "Exchange" or "EDGX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6)(iii) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to: (i) Amend the description of Price

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6)(iii).

Improving Orders under subparagraph (6) to Rule 21.1(d); and (ii) add subparagraph (4) to Rule 21.1(h) modifying the operation of orders subject to the display price sliding process when a contra-side Post Only Order[5] is received by the Exchange's options platform ("EDGX Options").

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to: (i) Amend the description of Price Improving Orders under subparagraph (6) to Rule 21.1(d); and (ii) add subparagraph (4) to Rule 21.1(h) modifying the operation of orders subject to the display price sliding process when a contra-side Post Only Order is received by EDGX Options.

Price Improving Orders

Price Improving Orders are orders to buy or sell an option at a specified price at an increment smaller than the minimum price variation in the security.[6] Price Improving Orders may be entered in increments as small as (1) one cent. Price Improving Orders are displayed at the minimum price variation in the security and shall be rounded up for sell orders and rounded down for buy orders. Unless a User[7] has entered instructions not to do so, Price Improving Orders are subject to the "display-price sliding process" described in current Rule 21.1(h).

As described above, Price Improving Orders may be priced at an increment smaller than the minimum price variation in the security (*i.e.,* for options priced in five (5) cent or ten (10) cent increments, an order priced at 1.03 is not a permissible increment for display). This may result in the order being ranked on the EDGX Options Book[8] non-displayed at a price increment smaller than the security's minimum price variation. The Exchange proposes to amend the description of Price Improving Orders under subparagraph (6) to Rule 21.1(d) to prevent Price Improving Orders subject to the Price Adjust process[9] from being ranked at a non-displayed price on the EDGX Options Book. The Exchange also proposes to amend subparagraph (6) to Rule 21.1(d) to clarify how Price Improving Orders subject to the display price sliding process are currently handled on the EDGX Options Book.

First, the Exchange proposes to amend the description of Price Improving Orders under subparagraph (6) to Rule 21.1(d) to prevent Price Improving Orders subject to the Price Adjust process from being ranked at a non-displayed price on the EDGX Options Book. Under the Price Adjust process, an order that, at the time of entry, would lock or cross a Protected Quotation of another options exchange or the Exchange will be ranked and displayed by the System at one minimum price variation below the current NBO (for bids) or to one minimum price variation above the current NBB (for offers). This could result in Price Improving Orders in securities with minimum quoting increments of five (5) or ten (10) cents[10] that the User elected to be subject to the Price Adjust process to be ranked on the EDGX Options Book at a non-displayed price. To prevent such orders from being ranked at a non-displayed price, the Exchange proposes to amend subparagraph (6) to Rule 21.1(d) to state that Price Improving Orders subject to the Price Adjust process will be ranked at the displayed price. Thus, other than a potential execution against contra-side liquidity when entered, a Price Improving Order subject to the Price Adjust process will no longer be priced at an increment smaller than the minimum price variation in the security.

The following examples describe the proposed operation of Price Improving Orders subject to the Price Adjust process.

Assume the NBBO is $1.00 x $1.05 and that the security's minimum quoting increment is five (5) cents. Further assume that there is no liquidity to sell resting on the EDGX Options Book at a price below $1.05. A Price Improving Order to buy priced at $1.03 is entered and the User has elected the Price Adjust process. Under current functionality, the order will be ranked, non-displayed on the EDGX Options Book at $1.03, the price of the order, and displayed at $1.00. As proposed, the order would be ranked and displayed at $1.00, the displayed price.

Assume the same example as above except that when the Price Improving Order is entered (*i.e.,* an order to buy priced at $1.03 subject to the Price Adjust process) there is a resting Price Improving Order to sell ranked at a price of $1.03 (*i.e.,* an order subject to the display price sliding process). In this case, the Price Improving Order subject to the Price Adjust process would execute upon entry against the resting order at $1.03.

The Exchange also proposes to amend subparagraph (6) to Rule 21.1(d) to clarify how Price Improving Orders subject to the display price sliding process are currently handled on the EDGX Options Book. While the Exchange believes the current operation of Price Improving Orders is clear based on existing rules, the Exchange believes this clarification is necessary due to the proposed changes. Particularly, in light of the change proposed above regarding Price Improving Orders subject to the Price Adjust process, the Exchange proposes to add language to subparagraph (d)(6) clarifying the operation of Price Improving Orders subject to the display price sliding process. As proposed, Exchange Rule 21.1(d)(6) would state that Price Improving Orders subject to the display-price sliding process will be ranked at the price entered by the User down to the current NBB (for offers) or up to the current NBO (for bids). The proposed language would make clear the current operation of such orders vis-a vis the proposed operation of Price Improving Orders subject to the Price Adjust process.

Display Price Sliding Process and Post Only Orders

Under current Exchange Rule 21.1(h), an order subject to the display price sliding process that, at the time of entry, would lock or cross a Protected Quotation of another options exchange will be ranked at the locking price in the EDGX Options Book and displayed by the System at one minimum price variation below the current National Best Offer ("NBO") [11] (for bids) or to one minimum price variation above the current National Best Bid ("NBB") [12] (for offers). Post Only Orders are orders that are to be ranked and executed on the Exchange pursuant to Rule 21.8 (Order Display and Book Processing) or cancelled, as appropriate, without routing away to another trading center.[13] Currently, a Post Only Order will not remove liquidity from the EDGX Options Book unless the value of price improvement associated with such execution equals or exceeds the sum of fees charged for such execution and the value of any rebate that would be provided if the order posted to the EDGX Options Book and subsequently provided liquidity. In order to prevent circumstances on the EDGX Options Book where an order is ranked at the displayed price of a resting contra-side order, which could result in apparent violations of the Exchange's priority rule, an incoming Post Only Order is currently rejected if it would be posted at the locking price of a contra-side order subject to the display price sliding process. In particular, accepting such order would result in a situation where an order is displayed on the Exchange and a contra-side order is ranked at the same price as such order. In turn, if an execution at that price is reported by the Exchange, the Exchange believes a User representing the order displayed on the Exchange might believe that an incoming order was received by the Exchange and then bypassed such order (*i.e.*, removing some other liquidity on the same side of the market as the displayed order). As described in further detail below, the proposal will avoid the possibility of an execution of an order subject to display-price sliding at the same price as an order displayed on the Exchange. The Exchange notes that the circumstance described above, where an incoming Post Only Order is rejected by the Exchange, is limited to times when the Exchange is not already quoting at the NBBO and a Post Only Order is seeking to join either the NBB or NBO but there is a resting display-price slid order on the contra-side of the Exchange's order book.

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[5] *See* Exchange Rule 21.1(d)(8).

[6] *See* Exchange Rule 21.1(d)(6).

[7] The term "User" means any Options Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3 (Access). *See* Exchange Rule 16.1(a)(63).

[8] "EDGX Options Book" is defined as "the electronic book of options orders maintained by the Trading System." *See* Exchange Rule 16.1(a)(9).

[9] *See* Exchange Rule 21.1(i).

[10] *See* Exchange Rule 21.5 for a description of the Exchange's Minimum Increments.

In order to facilitate the entry of orders priced at the National Best Bid or Offer ("NBBO"), the Exchange proposes to add subparagraph (4) to Rule 21.1(h) modifying the operation of orders subject to the display price sliding process when a contra-side Post Only Order is received by EDGX Options. Under proposed subparagraph (4), to the extent an incoming Post Only Order would be ranked and displayed at a price equal to the ranked price of a contra-side order subject to display-price sliding (*i.e.*, the locking price) the order subject to display-price sliding would be re-ranked at one (1) cent above the current NBB (for offers) or one (1) cent below the current NBO (for bids). An order subject to display price sliding that is re-ranked pursuant to proposed subparagraph (4) of Rule 21.1(h) would be re-ranked at the locking price in the event there is no longer displayed contra-side interest at the locking price. In both cases, the order would remain displayed by the System at one minimum price variation below the current NBO (for bids) or to one minimum price variation above the current NBB (for offers).

The below examples describe the operation of orders subject to display price sliding under proposed subparagraph (4) to Rule 21.1(h).

Example 1: Securities Quoted in Penny Increments—Proposed Operation. Assume the NBBO is $1.00 x $1.01 and that the Exchange's displayed best bid and offer ("BBO") is $1.00 x $1.02. Also assume that a non-routable order to buy at $1.01 subject to display price sliding is resting on the EDGX Options Book, ranked at $1.01 and displayed at $1.00. Assume a Post Only Order to sell at $1.01 is entered and, under current functionality, would be rejected because it is executable at the locking price of the order to buy subject to display price sliding resting on the EDGX Options Book. As proposed, the order to buy subject to display price sliding would be re-ranked and would remain displayed at $1.00, one (1) cent below the current NBO. The Post Only Order to sell would be posted to the EDGX Options Book, ranked and displayed at $1.01 (*i.e.*, allowing the Exchange to join the NBBO of $1.00 x $1.01). If the Post Only Order to sell is executed or cancelled, the order to buy subject to display price sliding would be re-ranked at $1.01, its original ranked price, and would remain displayed at $1.00.

Example 2: Securities Quoted in Non-Penny Increments—Proposed Operation. Assume the NBBO is $1.00 x $1.05 and that the Exchange's BBO is $1.00 x $1.10. Also assume that a non-routable order to buy at $1.05 subject to display price sliding is resting on the EDGX Options Book, ranked at $1.05 and displayed at $1.00. Assume a Post Only Order to sell at $1.05 is entered and, under current functionality, would be rejected because it is executable at the locking price of the order to buy subject to display price sliding resting on the EDGX Options Book. As proposed, the order to buy subject to display price sliding would be re-ranked at $1.04, one (1) cent below the NBO, and would remain displayed at $1.00. The Post Only Order to sell would be posted to the EDGX Options Book, ranked and displayed at $1.05 (*i.e.*, allowing the Exchange to join the NBBO of $1.00 x $1.01). If the Post Only Order to sell is executed or cancelled, the order to buy subject to display price sliding would be re-ranked at $1.05, its original ranked price, and would remain displayed at $1.00.

The Exchange notes that similar behavior currently exists on the Bats BZX Exchange, Inc. ("BZX") equities platform that permits an order to buy(sell) subject to display price sliding to be executed at one-half minimum price variation more(less) than the price of a contra-side displayed BZX Post Only Order.[14] Specifically, under BZX Rule 11.9(g)(1)(E), BZX Post Only Orders are permitted to post and be displayed opposite the ranked price of orders subject to display-price sliding. In the event an order subject to display-price sliding is ranked on the BZX Book [15] at a price equal to an opposite side order displayed by the Exchange, it cannot be executed at that price and instead will be subject to processing as set forth in BZX Rule 11.13(a)(4)(D). Under BZX Rule 11.13(a)(4)(D), in the event that an incoming order is a market order or is a limit order priced more aggressively than the displayed order, BZX will execute the incoming order at, in the case of an incoming sell order, one-half minimum price variation less than the price of the displayed order, and, in the case of an incoming buy order, at one-half minimum price variation more than the price of the displayed order. This behavior is designed to avoid an apparent priority issue. In particular, in such a situation the Exchange believes a User representing an order that is displayed on the Exchange might believe that an incoming order was received by the Exchange and then bypassed such displayed order, removing some other non-displayed liquidity on the same side of the market as such displayed order. Similar to what the Exchange proposes for EDGX Options, the above described functionality on its equites platform also effectively changes the ranked price of the order subject to display price sliding. Although the underlying solution is intended to solve the same circumstance, because half-penny executions are not permitted with respect to options transactions, on EDGX Options the Exchange proposes to adjust the ranked price of the display-price slid order when a contra-side Post

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[11] *See* Exchange Rule 16.1(a)(29) (defining the terms "NBB", "NBO", and "NBBO").

[12] *Id.*

[13] *See* Exchange Rule 21.1(d)(8).

[14] *See* BZX Rule 11.9(c)(6).

[15] *See* BZX Rule 1.5(e).

Only order is received by EDGX and posted at the locking price.

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[16] In particular, the proposal is consistent with Section 6(b)(5) of the Act[17] because it is designed to encourage displayed liquidity and offer market participants greater flexibility to post liquidity on the EDGX Options Book, thereby promoting just and equitable principles of trade, fostering cooperation and coordination with persons engaged in facilitating transactions in securities, removing impediments to, and perfecting the mechanism of, a free and open market and a national market system.

Price Improving Orders

The proposed changes to the description of Price Improving Orders under Rule 21.1(d)(6) promote just and equitable principles of trade and foster cooperation and coordination with persons engaged in facilitating transactions in securities. Specifically, the proposed change regarding Price Improving Orders subject to the Price Adjust process is designed to prevent the possibility of an internally crossed book where a Price Improving Order has already been submitted and is ranked non-displayed by the Exchange and a Post Only Order subject to the Price Adjust process is entered at a price increment smaller than the security's minimum price increment and that crosses the resting order.

In addition, the proposed amendment to Exchange Rule 21.1(d)(6) to clarify that Price Improving Orders subject to the display-price sliding process will be ranked at the price entered by the User down to the current NBB (for offers) or up to the current NBO (for bids) also promotes just and equitable principles of trade because it is consistent with and further clarifies the current operation of such orders. In addition, the addition of such language should avoid potential investor confusion regarding the operation of such orders with regard to the proposed language amending the operation of Price Improving Orders subject to the Price Adjust process.

Display Price Sliding Process and Post Only Orders

Under current functionality, an incoming Post Only Order would be rejected if it is executable at the locking price of a contra-side order subject to display price sliding resting on the EDGX Options Book. This, at times, inhibits market participants, including Market Makers[18] from utilizing Post Only Orders to quote at the NBBO. Post Only Orders allow Users to post aggressively priced liquidity, as such Users have certainty as to the fee or rebate they will receive from the Exchange if their order is executed. Without such ability and by rejecting such Post Only Orders in scenarios described herein, the Exchange believes that certain Users would simply post less aggressively priced liquidity, and prices available for market participants, including retail investors, would deteriorate. Accordingly, the Exchange believes that the proposed rule change promotes just and equitable principles of trade by enhancing the liquidity available to all market participants by allowing Market Makers and other liquidity providers to add liquidity to the Exchange at the NBBO without fear that their order would be rejected. In addition, the proposed rule change would assist Market Makers in satisfying their two-sided quoting obligations under Exchange Rules 22.5(a)(1) and 22.6(d)(1). The proposed rule change should increase displayed liquidity at the NBBO on the Exchange, resulting in improved market quality and price discovery for all participants. The Exchange also notes that similar behavior currently exists on BZX's equities platform that permits an order to buy(sell) subject to display price sliding to be executed at one-half minimum price variation more(less) than the price of a contra-side displayed BZX Post Only Order.[19]

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes the proposed rule change regarding display price sliding and Post Only Orders would enhance competition by enabling market participants to post liquidity at the NBBO, thereby increasing the liquidity on the Exchange at the NBBO. In addition, the Exchange believes the proposed amendments to Price Improving Orders would does not impact competition, but rather seeks to avoid the potential of an internally crossed book on the Exchange as well as to further clarify the operation of such orders when subject to the display price sliding process. For all the reasons stated above, the Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, and believes the proposed change will enhance competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[20] and Rule 19b–4(f)(6) thereunder.[21] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[22] and Rule 19b–4(f)(6) thereunder.[23]

A proposed rule change filed under Rule 19b–4(f)(6) under the Act[24] normally does not become operative for 30 days after the date of filing. However,

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[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] *See* Exchange Rule 16.1(a)(37).

[19] *See* BZX Rules 11.9(g)(1)(E) and 11.13(a)(4)(D). *See also* Securities Exchange Act Release No. 64754 (June 27, 2011), 76 FR 38712 (July 1, 2011) (SR–BATS–2011–015) (Order Approving a Proposed Rule Change to Amend BATS Rule 11.9, Entitled "Orders and Modifiers" and BATS Rule 11.13, Entitled "Order Execution").

[20] 15 U.S.C. 78s(b)(3)(A)(iii).

[21] 17 CFR 240.19b–4(f)(6).

[22] 15 U.S.C. 78s(b)(3)(A).

[23] In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[24] 17 CFR 240.19b–4(f)(6).

Rule 19b–4(f)(6)(iii) [25] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that the proposed rule change will benefit market participants by enhancing their ability to post liquidity at the NBBO, and that waiver of the operative delay may increase displayed liquidity at the NBBO on the Exchange, resulting in improved market quality and price discovery for all participants in a timely manner. Further, the Exchange notes that the proposed rule change will not require any systems changes by Exchange Users that would necessitate a delay, as the Exchange will now accept and no longer reject Post Only Orders in the situations described herein. Based on the foregoing, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest.[26] The Commission hereby grants the Exchange's request and designates the proposal operative upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BatsEDGX–2016–17 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR-BatsEDGX–2016–17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsEDGX–2016–17 and should be submitted on or before June 8, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–11642 Filed 5–17–16; 8:45 am]

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[25] 17 CFR 240.19b–4(f)(6)(iii).

[26] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736

Extension: Rule 13e–1

SEC File No. 270–255, OMB Control No. 3235–0305

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Rule 13e–1 (17 CFR 240.13e–1) under the Securities Exchange Act of 1934 (U.S.C. 78 *et seq.*) makes it unlawful for an issuer who has received notice that it is the subject of a tender offer made under Section 14(d)(1) of the Exchange Act to purchase any of its equity securities during the tender offer, unless it first files a statement with the Commission containing information required by the rule. This rule is in keeping with the Commission's statutory responsibility to prescribe rules and regulations that are necessary for the protection of investors. Public companies are the respondents. We estimate that it takes approximately 10 burden hours per response to provide the information required under Rule 13e–1 and that the information is filed by approximately 10 respondents. We estimate that 25% of the 10 hours per response (2.5 hours) is prepared by the company for a total annual reporting burden of 25 hours (2.5 hours per response × 10 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: May 12, 2016.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–11639 Filed 5–17–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77822; File No. SR–CBOE–2016–043]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule To Amend the Fees Schedule

May 12, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 2, 2016, Chicago Board Options Exchange, Incorporated (the "Exchange" or "CBOE") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Frequent Trader Program. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule. On April 1, 2016, the Exchange adopted a program that offers transaction fee rebates to Customers (origin code "C") that meet certain volume thresholds in CBOE VIX Volatility Index options ("VIX options") and S&P 500 Index options ("SPX"), weekly S&P 500 options ("SPXW") and p.m.-settled SPX Index options ("SPXpm") (collectively referred to as "SPX options") provided the Customer registers for the program (the "Frequent Trader Program" or "Program").[3]

To participate in the Frequent Trader Program, Customers register with the Exchange. Once registered, the Customer is provided a unique identification number ("FTID") that can be affixed to each of its orders. The FTID allows the Exchange to identify and aggregate all electronic and manual trades during both the Regular Trading Hours and Extended Trading Hours sessions from that Customer for purposes of determining whether the Customer meets any of the various volume thresholds. The Customer has to provide its FTID to the Trading Permit Holder ("TPH") submitting that Customer's order to the Exchange (executing agent" [sic] or "executing TPH") and that executing TPH would have to enter the Customer's FTID on each of that Customer's orders.[4] As there are instances in which a Customer's FTID was not or could not be, affixed to an order, the Exchange also provided executing TPHs the ability to submit to the exchange [sic] a form (the "Frequent Trader Program—Volume Corrections Form" or "Corrections Form") that would provide a mechanism for executing TPHs to identify transactions to the Exchange that should have been, but were not, associated with particular FTIDs. More specifically, the executing TPH can identify on the form the "correct" FTID that should be associated with a specific transaction, so that such volume is properly counted towards the appropriate Customer's aggregated volume for purposes of determining what tier, if any, the customer meets. Currently, the Fees Schedule provides that the Corrections Form must be submitted to the Exchange within 3 business days in order to ensure timely processing ("3 business day rule").

The Exchange now proposes to provide that for the month of April 2016, it will not enforce the requirement that the Corrections Form be submitted within 3 business days and instead provide that the Corrections Form will be accepted through May 4, 2016 (by 5:00 p.m. CST), for all transactions, regardless of when in April the transaction(s) occurred. Specifically, the Exchange notes that a number of executing TPHs were unable to (i) affix FTIDs onto their Customers' orders and (ii) complete and submit the Corrections Form within 3 business days for their Customers registered in the Frequent Trader Program. Many TPHs are still familiarizing themselves with this new program and its requirements and as such the Exchange desires to give them additional time to implement their systems and procedures, including their systems and procedures related to completing and submitting the Corrections Form. Additionally, the Exchange does not wish to penalize the Customers who would miss out on rebates they would otherwise be entitled to if the deadline is not extended. Accordingly, the Exchange does not wish to enforce the 3 business day rule for April 2016. The Exchange believes providing additional time to submit Corrections Forms will ensure Customers are not unfairly deprived of any rebates that they are entitled to under the Frequent Trader Program for the month of April.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[5] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[6] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes not enforcing the 3 business day rule for the month of April 2016 provides executing TPHs additional time to submit Corrections Forms, which removes impediments to and perfects the mechanism of a free and open market and a national market system, and protects investors and the public interest as it avoids penalizing Customers who would otherwise miss out on rebates they are entitled to under the Frequent Trader Program. Corrections Forms allow the Exchange to ensure that a customer's total volume at the end of the month accurately reflects their real trading volume, including volume from transactions that, upon submission of the order, did not reflect their FTID. As noted above, many TPHs are still in the process of familiarizing themselves with the new Frequent Trader Program and its requirements and do not yet have the systems or procedures in place to process the Corrections Forms within the timeframe the Exchange initially required. As such, the Exchange does not believe it would be fair to the Customers to enforce the 3 business day rule for the first month of the Frequent Trader Program (*i.e.,* April 2016). Additionally, waiving the 3 business day rule for April 2016 eliminates confusion in that it gives the executing TPHs extra time to understand the requirements of the Program and implement policies, procedures, and system changes needed to properly take advantage of the program, which again removes impediments to and perfects the mechanism of a free and open market and a national market system, and protects investors and the public interest.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* SR–CBOE–2016–023.

[4] The Exchange notes that it is the responsibility of the Customer to request that the executing TPH affix its FTID to its order(s), and that it is voluntarily for the executing TPH to do so.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] *Id.*

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed change applies uniformly to all executing TPHs of Customer FTID orders and because it provides for a clear process to rectify scenarios in which a FTID(s) were not or could not be applied to Customer's order and where Corrections Forms were not submitted in a timely manner in April 2016. The Exchange believes that the proposed rule change will not cause an unnecessary burden on intermarket competition because it only applies to trading on CBOE. To the extent that the proposed changes make CBOE a more attractive marketplace for market participants at other exchanges, such market participants are welcome to become CBOE market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and Rule 19b–4(f)(6) thereunder.[9]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[10] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[11] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. Consistent with the protection of investors and the public interest, waiver of the 30-day operative delay will provide TPHs with additional time (to May 4) to submit Corrections Forms for participating Customer transactions that occurred in April under the new Frequent Trader Program, which should help TPHs acclimate to the new process for submitting their participating Customer trades to CBOE and thereby ensure that their April volume under the program accurately reflects their trading volume. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[12]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2016–043 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2016–043. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2016–043, and should be submitted on or before June 8, 2016.

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[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6). Rule 19b–4(f)(6)(iii) requires the Exchange to provide the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission has determined to waive the five business day requirement.

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6)(iii).

[12] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–11645 Filed 5–17–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77823; File No. SR–CBOE–2016–034]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Split-Price Priority

May 12, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 6, 2016, Chicago Board Options Exchange, Incorporated (the "Exchange" or "CBOE") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules related to split-price priority. The text of the proposed rule change is provided below.

(additions are *italicized;* deletions are [bracketed])

* * * * *

Chicago Board Options Exchange, Incorporated Rules

* * * * *

Rule 1.1. Definitions

When used in these Rules, unless the context otherwise requires:

(a)–(eee) No change.

Voluntary Professional

(fff) The term "Voluntary Professional" means any person or entity that is not a broker or dealer in securities that elects, in writing, to be treated in the same manner as a broker or dealer in securities for purposes of Rules 6.2A, 6.2B, 6.8C, 6.9, 6.13A, 6.13B, 6.25, 6.45, 6.45A (except for Interpretation and Policy .02), 6.45B (except for Interpretation and Policy .02), *6.47,* 6.53C(c)(ii), 6.53C(d)(v), subparagraphs (b) and (c) under Interpretation and Policy .06 to Rule 6.53C, 6.74 (except Voluntary Professional orders may be considered public customer orders subject to facilitation under paragraphs (b) and (d)), 6.74A, 6.74B, 8.13, 8.15(d), 8.87, 24.19, 43.1, 44.4, 44.14, and for cancellation fee treatment. The Voluntary Professional designation is not available in Hybrid 3.0 classes.

Professional

(ggg) The term "Professional" means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). A Professional will be treated in the same manner as a broker or dealer in securities for purposes of Rules 6.2A, 6.2B, 6.8C, 6.9, 6.13A, 6.13B, 6.25, 6.45, 6.45A (except for Interpretation and Policy .02), 6.45B (except for Interpretation and Policy .02), *6.47,* 6.53C(c)(ii), 6.53C(d)(v), subparagraphs (b) and (c) under Interpretation and Policy .06 to Rule 6.53C, 6.74 (except Professional orders may be considered public customer orders subject to facilitation under paragraphs (b) and (d)), 6.74A, 6.74B, 8.13, 8.15(d), 8.87, 24.19, 43.1, 44.4, 44.14. The Professional designation is not available in Hybrid 3.0 classes. All Professional orders shall be marked with the appropriate origin code as determined by the Exchange.

. . . *Interpretations and Policies:*

.01 No change.

(hhh)—(sss) No change.

. . . *Interpretations and Policies:*

.01—.05 No change.

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Rule 6.47. Priority on Split-Price Transactions Occurring in Open Outcry

(a) [Purchase or sale]*Split-Price* [p]*P*riority. If *an order or offer (bid) for any number of contracts of a series is represented to the crowd,* a Trading Permit Holder *that buys* [purchases] (sells) one or more [option]contracts of *that order or offer (bid)*[a particular series] at *one*[a particular] price[or prices, he shall, at the next lower (higher) price at which a Trading Permit Holder other than the Order Book Official is bidding (offering),] *will* have priority [in] *over all other orders and quotes, except public customer orders resting in the book, to buy* [purchasing](sell[ing]) up to the [equivalent]*same* number of [option] contracts of *those remaining from* the same *order or offer (bid)*[series that he purchased (sold)] at the *next lower (*higher[(lower]) price[or prices, but only if his bid (offer) is made promptly and the purchase (sale) so effected represents the opposite side of a transaction with the same order or offer (bid) as the earlier purchase or purchases (sale or sales). This paragraph only applies to transactions effected in open outcry].

(b) [Purchase or sale]*Split-Price* [p]*P*riority for *O*[o]rders *or Offers (Bids)* of 100 *or More* [c]*C*ontracts[or more]. If *an order or offer (bid) of 100 or more contracts of a series is represented to the crowd,* a Trading Permit Holder *that buys*[purchases] (sells) *50*[fifty] or more *of the* [option]contracts of *that order or offer (bid)*[a particular series] at *one*[a particular] price [or prices, he shall, at the next lower (higher) price]*will* have priority [in]*over all other orders and quotes to buy* [purchasing](sell[ing]) up to the [equivalent]*same* number of [option]contracts of *those remaining from* the same [series that he purchased (sold)]*order or offer (bid)* at the *next lower (*higher[(lower]) price[or prices, but only if his bid (offer) is made promptly and the purchase (sale) so effected represents the opposite side of a transaction with the same order or offer (bid) as the earlier purchase or purchases (sale or sales)]. The Exchange may increase the ["]minimum qualifying [order]size[" above] *of* 100 contracts on a class-by-class basis[.], [Announcements regarding]*which* changes [to the minimum qualifying order size shall be made]*the Exchange will announce* via Regulatory Circular.[This paragraph only applies to transactions effected in open outcry.]

(c) Two or [m]*M*ore Trading Permit Holders [e]*E*ntitled to [p]*P*riority. If the bids or offers of two or more Trading Permit Holders are both entitled to *split-price* priority[in accordance with paragraph (a) or paragraph (b)], it [shall]*will* be afforded [them insofar as]*to the extent* practicable[,] on a pro-rata basis.

(d) Conditions. Split-price priority is subject to the following:

(i) The priority is available for open outcry transactions only and does not apply to complex orders.

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[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

(ii) The Trading Permit Holder must make its bid (offer) at the next lower (higher) price for the second (or later) transaction at the same time as the first bid (offer) or promptly following execution of the first (or earlier) transaction.

(iii) The second (or later) purchase (sale) must represent the opposite side of a transaction with the same order or offer (bid) as the first (or earlier) purchase (sale).

(e) Minimum Increment Width with Public Customer Orders Resting in the Book. If the width of the quote for a series is the minimum increment for that series, and both the bid and offer represent public customer orders resting in the book, split-price priority pursuant to this rule is not available to Trading Permit Holders until the public customer order(s) resting in the book on either side of the market trades.

. . . Interpretations and Policies:

.01–.02 No change.

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The text of the proposed rule change is also available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Rule 6.47 establishes priority principles for split-price transactions occurring in open outcry. Generally, a Trading Permit Holder that purchases (sells) one or more contracts of a series at a particular price will have priority over other Trading Permit Holders, other than those representing orders in the limit order book, in purchasing (selling) up to an equivalent number of contracts of the same order at the next lower (higher) price. For orders of 100 or more contracts, Trading Permit Holders that trade 50 or more contracts of such orders at a particular price will have this priority over all other Trading Permit Holders at the next best price, including those representing orders in the limit order book. This priority is awarded for split-price transactions that occur in open outcry only.

Minimum Increment Width Series

The Exchange proposes to add Rule 6.47(e) to codify an exception to the availability of split-price priority when the width of a series' quote is at the minimum increment width. If the width of the quote for a series is the minimum increment for that series (*e.g.,* $1.00–$1.05 for a series with a minimum increment of $0.05, $1.00–$1.01 for a series with a minimum increment of $0.01), and both the bid and offer represent public customer orders resting in the book, split-price priority pursuant to this rule is not available to Trading Permit Holders until the public customer order(s) resting in the book on either side of the market trades.[3] This exception is consistent with the Exchange's allocation and priority rules, which provide for public customer orders to have first priority at the best price in open outcry (subject to applicable exceptions).[4]

For example, assume the market for a series with a minimum increment of $0.05 is $1.00–$1.05 (with the $1.00 bid and $1.05 offer each representing a customer order for 25 contracts), and a Floor Broker receives an order from a customer that would like to buy 100 contracts at a price or prices no higher than $1.05. The Floor Broker attempts to execute the order in open outcry at a price better than the displayed offer of $1.05. Assume a Market-Maker is willing to sell 50 contracts at $1.00 and 50 contracts at $1.05. The "first transaction" of this split-price transaction would be 50 contracts at $1.00. However, there is customer interest resting at $1.00, which would have time priority to trade at $1.00.[5] Therefore, in this situation, if the Market-Maker wants to receive split-price priority at $1.05, the Market-Maker would not be able to execute the first part of a split-price transaction with the order being represented by the Floor Broker until after the resting customer order at $1.00 trades.

The proposed rule change provides that "either side of the market" must trade for split-price priority to become available. The rule provides that a Trading Permit Holder is eligible to receive split-price priority, which could include the Trading Permit Holder representing the order or offer (quote). Thus, the proposed rule change allows for the Trading Permit Holder on either side of a transaction to be eligible for split-price priority. Assume the market for a series with a minimum increment of $0.05 is $1.00–$1.05 (with the $1.00 bid and $1.05 offer each representing a customer order for 25 contracts), and a Floor Broker receives an order from a customer that would like to buy 100 contracts at a price or prices no higher than $1.05. After receiving no interest from the crowd to sell 100 contracts at $1.00, the Floor Broker represents to the crowd that it would like to buy 50 contracts at $1.00 and 50 contracts at $1.05. Assume a Market-Maker is willing to sell 50 contracts at $1.00 and 50 contracts at $1.05. In a separate transaction, the public customer order at $1.05 trades against an order of another market participant. The "first transaction" of this split-price transaction would be 50 contracts at $1.05 (at which price there is no more resting public customer offer) and the "second transaction" of this split-price transaction would be 50 contracts at $1.00, the next best price for the Floor Broker. In this situation, the Floor Broker is eligible to receive split-price priority at $1.00 over the resting customer interest at $1.00 and achieve a better net price execution of $1.025 for its customer order.

Other than the limited exception to customer priority afforded in Rule 6.47(b) (and as elsewhere set forth in the rules),[6] public customer orders continue to have first priority and other allocation and priority rules remain unchanged. The Exchange believes that specifying the unavailability of split-price priority in this specific situation will further clarify the applicability of the priority in the rules.

Multiple Prices

Rule 6.47(a) and (b) currently provides that split-price priority may apply to executions of an order at multiple prices. The proposed rule change removes the references to multiple prices from those paragraphs. The Exchange believes the priority should only apply at the next price level rather than multiple price levels.

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[3] This exception is currently set forth in Regulatory Circular RG07–076.

[4] *See* Rules 6.45A(b)(i)(A) and 6.45B(b)(i)(A).

[5] *See id.*

[6] For example, the rules provide for a complex order priority exception (*see* Rules 6.45(e), 6.45A(b)(ii) and 6.45B(b)(ii).

Nonsubstantive Changes

The Exchange proposes to make the following nonsubstantive changes to Rule 6.47(a), (b) and (c):

- The proposed rule change amends the headings of and adds introductory language to paragraphs (a) and (b).
- The proposed rule change revises the language in paragraphs (a) and (b) to simplify the description of when the split-price priority applies to improve readability. The priority will still apply in the same manner—a Trading Permit Holder may buy (sell) one or more contracts for one series of an order or offer (bid) (the "first transaction")[7] and receive priority over all other orders and quotes (except public customer orders resting in the book with respect to orders or offers (bids) of fewer than 100 contracts or orders or offers (bids) with which Trading Permit Holders do not purchase (sell) at least 50 contracts at the better price) to buy (sell) up to the same number of contracts of those remaining from the same order or offer (bid) at the next best price (the "second transaction"). This second transaction must still occur with the same order or offer (quote) as the first transaction. For example, assume the market is $1.00–$1.20 with size of 300 contracts, and a Floor Broker receives an order from a customer that would like to buy 500 contracts at a price or prices no higher than $1.20. The Floor Broker attempts to execute the order in open outcry at a price better than the displayed offer of $1.20. Now assume a Market-Maker in the crowd is willing to sell 250 contracts at $1.15 and 250 contracts at $1.20. The Market-Maker could offer $1.15 for 250 contracts and then, by virtue of the split-price priority rule, have priority for the 250 contract balance over other crowd members at $1.20. The resulting net execution price for the customer would be $1.175, which is better than the displayed market of $1.20 and thus a better fill for the customer.[8]
- Paragraph (a) currently provides that the Trading Permit Holder must yield to the Order Book Official. The proposed rule change amends the term Order Book Official to public customer. Other priority rules refer to "public customer" priority,[9] and Rule 6.47(a) provides priority in the circumstances described except over public customer orders.[10] Order Book Officials only present to the crowd public customer orders that rest in the book, so the priority afforded pursuant to paragraph (a) must still yield to the same public customer orders in the same manner. This change is merely an update to terminology, as public customer orders may be presented to the floor other than by Order Book Officials.[11] The Exchange believes it is appropriate to use the same terminology that is used in other priority rules to ensure consistency throughout the Exchange's rules and ensure that all public customer orders receive priority when applicable.
- Paragraphs (a) and (b) currently state that a Trading Permit Holder's bid (offer) at the next best price must be made promptly following the purchase (sale) at the initial price. The proposed rule change deletes that language from those paragraphs and adds it to new paragraph (d) to include with other conditions to which split-price priority is subject. In addition, the proposed rule change adds that the second bid (offer) may also be made at the same time as the first bid (offer). If a Trading Permit Holder makes the first bid (offer) with the intent of taking advantage of the split-price priority, then it may be more efficient for the Trading Permit Holder to announce both bids (offers) at the same time than to wait for the first execution.[12] The Trading Permit Holder is still not guaranteed execution at the second price; another Trading Permit Holder may still bid (offer) to trade with part of the order or offer (quote) at the better first price.
- Paragraphs (a) and (b) currently state that they apply only to open outcry transactions. The proposed rule change deletes that language from those paragraphs and adds it to new paragraph (d) to include with other conditions to which split-price priority is subject. Paragraphs (a) and (b) also state that split-price priority applies to transactions in a particular series (*i.e.* simple orders, but not complex orders). The proposed rule change explicitly states the priority does not apply to complex orders in new paragraph (d).
- Paragraphs (a) and (b) currently state that the Trading Permit Holder eligible for split-price priority must make its bid (offer) promptly and the purchase (sale) represents the opposite side of a transaction with the same *order or offer (bid)*. The proposed rule change uses this phrase throughout the rule for consistency. The proposed rule change also deletes the provision that requires the subsequent transaction must be with the same order or offer (bid) from paragraphs (a) and (b) and adds it to new paragraph (d).
- The proposed rule change makes other administrative and clerical changes to paragraphs (a), (b) and (c) (*e.g.*, capitalizing words in headings, changing the word purchase to buy, deletion of word option before contract since only option contracts execute on the Exchange). The Exchange believes these changes have no impact on the split-price priority afforded by the rule.
- The proposed rule change refers to the priority afforded by Rule 6.47(a) and (b) as "split-price priority" to further simplify the rule text.

The Exchange believes these nonsubstantive changes more clearly describe the applicability of the split-price priority and better reflect the use of split-price priority on the trading floor.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[13] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[14] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[15] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

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[7] The Exchange notes that the current rule contemplates that an order or quote can represent the series with which a Trading Permit Holder may transact to receive split-price priority. The current rule uses the phrase "contracts of a particular series," which includes both orders and quotes, and indicates that the purchase (sale) effected represents the opposite side of a transaction with the "same order or offer (bid)" as the earlier purchase (sale), which again contemplates multiple transactions with a single originating order or quote. The proposed rule change makes clear throughout that an order or quote can comprise the originating contracts with which the crowd can trade to obtain split-price priority.

[8] While the net price result will be $1.175, two separate trades at $1.15 and $1.20 would be reported.

[9] *See, e.g.,* Rules 6.45A(b)(i)(A) and 6.45B(b)(i)(A).

[10] The proposed rule change amends Rule 1.1(fff) and (ggg) to add Rule 6.47 to the list of rules for which Voluntary Professionals and Professionals, respectively, will be treated in the same manner as a broker or dealer. Professionals and Voluntary Professionals do not receive priority as public customers do pursuant to CBOE's allocation rules, including Rules 6.45A(b) and 6.45B(b) regarding open outcry trading. Under those rules, Professionals and Voluntary Professionals would not receive priority, including if public customer orders must be cleared prior to a Trading Permit Holder availing itself of split-price priority. The proposed rule change explicitly states this in the Professional and Voluntary Professional definitions.

[11] Additionally, the Exchange no longer has Order Book Officials.

[12] For example, a Floor Broker may represent an order to sell at "$1.15 and $1.20 splits," indicating a desire to buy half of the order at $1.15 and the other half at $1.20 with priority at $1.20.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

In particular, the Exchange believes the proposed rule change is consistent with the purpose of the existing split-price priority, which is to induce Trading Permit Holders to bid (offer) at better prices for an order or offer (bid) that may require execution at multiple prices (such as larger orders), which will result in a better average price for the originating Trading Permit Holder (or its customer).

The proposed rule change to codify the split-price priority exception when the width of a series' quote is the minimum increment for that series and each side of the quote represents public customer interest will benefit investors by including all information regarding when split-price priority is available in a single rule. This proposed rule change is consistent with the Exchange's priority and allocation rules. The Exchange believes the proposed rule change to codify this exception, as well as the proposed rule change to eliminate split-price priority at multiple price levels, balances the availability of split-price priority, which benefits investors by providing opportunities for price improvement, with customer priority, which promotes just and equitable principles of trade by providing public customers access to CBOE's market.

The proposed rule change to amend the definitions of Voluntary Professional and Professional clarify that, for purposes of Rule 6.47, as is the case for all other allocation rules, those participants will be treated as broker-dealers rather than public customers for allocation purposes. The same result occurs under current allocation rules, as those rules provide with respect to open outcry priority that public customers in the book receive priority (and the definitions of Voluntary Professional and Professional provide that those participants are treated as broker-dealers for purposes of those rules); this merely clarifies it in the Rules.

The Exchange believes the nonsubstantive changes to Rule 6.47 will benefit investors by describing the applicability of split-price priority more simply and clearly. The revised language is also more consistent with other Exchange rules regarding priority.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The priority afforded by Rules 6.47(a) and (b) continues to be available to all Trading Permit Holders who trade open outcry, of which all Trading Permit Holders that engage in open outcry trading may avail themselves. Rules often apply to open outcry trading only because of the different nature of the open outcry market versus the electronic market (such as allocation rules). The proposed rule change may result in better pricing for customer orders submitted to the trading floor, particularly those that may require execution at multiple prices, and market participants may submit orders to CBOE to take advantage of these better prices. CBOE believes that the proposed rule change will continue to encourage Trading Permit Holders on CBOE's trading floor to bid or offer better prices, thus creating more opportunities for price improvement, which ultimately enhances competition. The nonsubstantive changes and codification of the applicability of split-price priority in a minimum width market do not impact the manner in which split-price priority applies and thus have no effect on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[16] and Rule 19b–4(f)(6) thereunder.[17] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2016–034 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2016–034. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE.,

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[15] *Id.*

[16] 15 U.S.C. 78s(b)(3)(A)(iii).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2016–034, and should be submitted on or before June 8, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–11652 Filed 5–17–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736

Extension: Schedule 14D–9F
SEC File No. 270–339, OMB Control No. 3235–0382

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Schedule 14D–9F (17 CFR 240.14d–103) under the Securities Exchange Act of 1934 (15 U.S.C. 78 *et seq.*) is used by any foreign private issuer incorporated or organized under the laws of Canada or by any director or officer of such issuer, where the issuer is the subject of a cash tender or exchange offer for a class of securities filed on Schedule 14D–1F. The information required to be filed with the Commission is intended to permit verification of compliance with the securities law requirements and assures the public availability of such information. The information provided is mandatory and all information is made available to the public upon request. We estimate that Schedule 14D–9F takes approximately 2 hours per response to prepare and is filed by approximately 6 respondents annually for a total reporting burden of 12 hours (2 hours per response × 6 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: May 12, 2016.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–11640 Filed 5–17–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77818; File No. SR–BatsBZX–2016–16]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Add Subparagraph (5) to Rule 21.1(h) Modifying the Operation of Orders Subject to the Display Price Sliding Process When a Contra-Side Post Only Order Is Received by the Bats BZX Exchange Options Platform

May 12, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 3, 2016, Bats BZX Exchange, Inc. (the "Exchange" or "BZX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6)(iii) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to add subparagraph (5) to Rule 21.1(h) modifying the operation of orders subject to the display price sliding process when a contra-side Post Only Order[5] is received by the Exchange's options platform ("BZX Options").

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to add subparagraph (5) to Rule 21.1(h) modifying the operation of orders subject to the display price sliding process when a contra-side Post Only Order is received by BZX Options.

Under current Exchange Rule 21.1(h), an order subject to the display price sliding process that, at the time of entry, would lock or cross a Protected Quotation of another options exchange will be ranked at the locking price in the BZX Options Book[6] and displayed by the System at one minimum price variation below the current National

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[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6)(iii).

[5] *See* Exchange Rule 21.1(d)(8).

[6] "BZX Options Book" is defined as "the electronic book of options orders maintained by the Trading System." *See* Exchange Rule 16.1(a)(9).

Best Offer ("NBO")[7] (for bids) or to one minimum price variation above the current National Best Bid ("NBB")[8] (for offers). Post Only Orders are orders that are to be ranked and executed on the Exchange pursuant to Rule 21.8 (Order Display and Book Processing) or cancelled, as appropriate, without routing away to another trading center.[9] Currently, a Post Only Order will not remove liquidity from the BZX Options Book unless the value of price improvement associated with such execution equals or exceeds the sum of fees charged for such execution and the value of any rebate that would be provided if the order posted to the BZX Options Book and subsequently provided liquidity. In order to prevent circumstances on the BZX Options Book where an order is ranked at the displayed price of a resting contra-side order, which could result in apparent violations of the Exchange's priority rule, an incoming Post Only Order is currently rejected if it would be posted at the locking price of a contra-side order subject to the display price sliding process. In particular, accepting such order would result in a situation where an order is displayed on the Exchange and a contra-side order is ranked at the same price as such order. In turn, if an execution at that price is reported by the Exchange, the Exchange believes a User[10] representing the order displayed on the Exchange might believe that an incoming order was received by the Exchange and then bypassed such order (*i.e.,* removing some other liquidity on the same side of the market as the displayed order). As described in further detail below, the proposal will avoid the possibility of an execution of an order subject to display-price sliding at the same price as an order displayed on the Exchange. The Exchange notes that the circumstance described above, where an incoming Post Only Order is rejected by the Exchange, is limited to times when the Exchange is not already quoting at the NBBO and a Post Only Order is seeking to join either the NBB or NBO but there is a resting display-price slid order on the contra-side of the Exchange's order book.

In order to facilitate the entry of orders priced at the National Best Bid or Offer ("NBBO"), the Exchange proposes to add subparagraph (5) to Rule 21.1(h) modifying the operation of orders subject to the display price sliding process when a contra-side Post Only Order is received by BZX Options. Under proposed subparagraph (5), to the extent an incoming Post Only Order would be ranked and displayed at a price equal to the ranked price of a contra-side order subject to display-price sliding (*i.e.,* the locking price) the order subject to display-price sliding would be re-ranked at one (1) cent above the current NBB (for offers) or one (1) cent below the current NBO (for bids). An order subject to display price sliding that is re-ranked pursuant to proposed subparagraph (5) of Rule 21.1(h) would be re-ranked at the locking price in the event there is no longer displayed contra-side interest at the locking price. In both cases, the order would remain displayed by the System at one minimum price variation below the current NBO (for bids) or to one minimum price variation above the current NBB (for offers).

The below examples describe the operation of orders subject to display price sliding under proposed subparagraph (5) to Rule 21.1(h).

Example 1: Securities Quoted in Penny Increments—Proposed Operation. Assume the NBBO is $1.00 × $1.01 and that the Exchange's displayed best bid and offer ("BBO") is $1.00 × $1.02. Also assume that a non-routable order to buy at $1.01 subject to display price sliding is resting on the BZX Options Book, ranked at $1.01 and displayed at $1.00. Assume a Post Only Order to sell at $1.01 is entered and, under current functionality, would be rejected because it is executable at the locking price of the order to buy subject to display price sliding resting on the BZX Options Book. As proposed, the order to buy subject to display price sliding would be re-ranked and would remain displayed at $1.00, one (1) cent below the current NBO. The Post Only Order to sell would be posted to the BZX Options Book, ranked and displayed at $1.01 (*i.e.,* allowing the Exchange to join the NBBO of $1.00 × $1.01). If the Post Only Order to sell is executed or cancelled, the order to buy subject to display price sliding would be re-ranked at $1.01, its original ranked price, and would remain displayed at $1.00.

Example 2: Securities Quoted in Non-Penny Increments—Proposed Operation. Assume the NBBO is $1.00 × $1.05 and that the Exchange's BBO is $1.00 × $1.10. Also assume that a non-routable order to buy at $1.05 subject to display price sliding is resting on the BZX Options Book, ranked at $1.05 and displayed at $1.00. Assume a Post Only Order to sell at $1.05 is entered and, under current functionality, would be rejected because it is executable at the locking price of the order to buy subject to display price sliding resting on the BZX Options Book. As proposed, the order to buy subject to display price sliding would be re-ranked at $1.04, one (1) cent below the NBO, and would remain displayed at $1.00. The Post Only Order to sell would be posted to the BZX Options Book, ranked and displayed at $1.05 (*i.e.,* allowing the Exchange to join the NBBO of $1.00 × $1.01). If the Post Only Order to sell is executed or cancelled, the order to buy subject to display price sliding would be re-ranked at $1.05, its original ranked price, and would remain displayed at $1.00.

The Exchange notes that similar behavior currently exists on its equities platform that permits an order to buy(sell) subject to display price sliding to be executed at one-half minimum price variation more(less) than the price of a contra-side displayed BZX Post Only Order.[11] Specifically, under Exchange Rule 11.9(g)(1)(E), BZX Post Only Orders are permitted to post and be displayed opposite the ranked price of orders subject to display-price sliding. In the event an order subject to display-price sliding is ranked on the BZX Book[12] at a price equal to an opposite side order displayed by the Exchange, it cannot be executed at that price and instead will be subject to processing as set forth in Rule 11.13(a)(4)(D). Under Exchange Rule 11.13(a)(4)(D), in the event that an incoming order is a market order or is a limit order priced more aggressively than the displayed order, the Exchange will execute the incoming order at, in the case of an incoming sell order, one-half minimum price variation less than the price of the displayed order, and, in the case of an incoming buy order, at one-half minimum price variation more than the price of the displayed order. This behavior is designed to avoid an apparent priority issue. In particular, in such a situation the Exchange believes a User representing an order that is displayed on the Exchange might believe that an incoming order was received by the Exchange and then bypassed such displayed order, removing some other non-displayed liquidity on the same side of the market as such displayed order. Similar to what the Exchange proposes for BZX Options, the above described functionality on its equites platform also effectively changes the ranked price of the order subject to display price sliding. Although the underlying solution is intended to solve the same circumstance, because half-penny executions are not permitted with respect to options transactions, on BZX Options the Exchange proposes to adjust the ranked price of the display-price slid order when a contra-side Post Only order is received by BZX and posted at the locking price.

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[7] *See* Exchange Rule 16.1(a)(29) (defining the terms "NBB", "NBO", and "NBBO").

[8] *Id.*

[9] *See* Exchange Rule 21.1(d)(8).

[10] "User" is defined as "any Options Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3 (Access)." *See* Exchange Rule 16.1(a)(63).

[11] *See* Exchange Rule 11.9(c)(6).

[12] *See* BZX Rule 1.5(e).

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[13] In particular, the proposal is consistent with Section 6(b)(5) of the Act[14] because it is designed to encourage displayed liquidity and offer market participants greater flexibility to post liquidity on the BZX Options Book, thereby promoting just and equitable principles of trade, fostering cooperation and coordination with persons engaged in facilitating transactions in securities, removing impediments to, and perfecting the mechanism of, a free and open market and a national market system.

Under current functionality, an incoming Post Only Order would be rejected if it is executable at the locking price of a contra-side order subject to display price sliding resting on the BZX Options Book. This, at times, inhibits market participants, including Market Makers[15] from utilizing Post Only Orders to quote at the NBBO. Post Only Orders allow Users to post aggressively priced liquidity, as such Users have certainty as to the fee or rebate they will receive from the Exchange if their order is executed. Without such ability and by rejecting such Post Only Orders in scenarios described herein, the Exchange believes that certain Users would simply post less aggressively priced liquidity, and prices available for market participants, including retail investors, would deteriorate. Accordingly, the Exchange believes that the proposed rule change promotes just and equitable principles of trade by enhancing the liquidity available to all market participants by allowing Market Makers and other liquidity providers to add liquidity to the Exchange at the NBBO without fear that their order would be rejected. In addition, the proposed rule change would assist Market Makers in satisfying their two-sided quoting obligations under Exchange Rules 22.5(a)(1) and 22.6(d)(1). The proposed rule change should increase displayed liquidity at the NBBO on the Exchange, resulting in improved market quality and price discovery for all participants. The Exchange also notes that similar behavior currently exists on its equities platform that permits an order to buy(sell) subject to display price sliding to be executed at one-half minimum price variation more(less) than the price of a contra-side displayed BZX Post Only Order.[16]

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes the proposed rule change would enhance competition by enabling market participants to post liquidity at the NBBO, thereby increasing the liquidity on the Exchange at the NBBO. For all the reasons stated above, the Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, and believes the proposed change will enhance competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[17] and Rule 19b–4(f)(6) thereunder.[18] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[19] and Rule 19b–4(f)(6) thereunder.[20]

A proposed rule change filed under Rule 19b–4(f)(6) under the Act[21] normally does not become operative for 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii)[22] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that the proposed rule change will benefit market participants by enhancing their ability to post liquidity at the NBBO, and that waiver of the operative delay may increase displayed liquidity at the NBBO on the Exchange, resulting in improved market quality and price discovery for all participants in a timely manner. Further, the Exchange notes that the proposed rule change will not require any systems changes by Exchange Users that would necessitate a delay, as the Exchange will now accept and no longer reject Post Only Orders in the situations described herein. Based on the foregoing, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest.[23] The Commission hereby grants the Exchange's request and designates the proposal operative upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

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[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] *See* Exchange Rule 16.1(a)(37).

[16] *See* Exchange Rules 11.9(g)(1)(E) and 11.13(a)(4)(D). *See also* Securities Exchange Act Release No. 64754 (June 27, 2011), 76 FR 38712 (July 1, 2011) (SR–BATS–2011–015) (Order Approving a Proposed Rule Change to Amend BATS Rule 11.9, Entitled "Orders and Modifiers" and BATS Rule 11.13, Entitled "Order Execution").

[17] 15 U.S.C. 78s(b)(3)(A)(iii).

[18] 17 CFR 240.19b–4(f)(6).

[19] 15 U.S.C. 78s(b)(3)(A).

[20] In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[21] 17 CFR 240.19b–4(f)(6).

[22] 17 CFR 240.19b–4(f)(6)(iii).

[23] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BatsBZX–2016–16 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BatsBZX–2016–16. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsBZX–2016–16 and should be submitted on or before June 8, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–11641 Filed 5–17–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77817; File No. SR–MIAX–2016–10]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 612, Aggregate Risk Manager ("ARM")

May 12, 2016.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 29, 2016, Miami International Securities Exchange LLC ("MIAX" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Exchange Rule 612, Aggregate Risk Manager ("ARM").

The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/filter/wotitle/rule_filing*, at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. *Purpose*

The Exchange proposes to amend Exchange Rule 612, Aggregate Risk Manager ("ARM"), to modify the minimum Allowable Engagement Percentage (as described below) determined by Exchange Market Makers, and to codify the Exchange's existing practice of establishing default ARM settings, as described below. The Exchange is also proposing two minor technical amendments to Rule 612(a), as described below.

ARM protects MIAX Market Makers[3] and assists them in managing risk by limiting the number of contracts they execute in an option class on the Exchange within a specified time period that has been established by the Market Maker (a "specified time period"). MIAX Market Makers establish a percentage of their quotations (the "Allowable Engagement Percentage" or "AEP") and the specified time period for each option class in which they are appointed.[4] The System activates the Aggregate Risk Manager when it has determined that a Market Maker has traded a number of contracts equal to or above their AEP during the specified time period. When an execution against a Market Maker's Standard quote[5] or Day eQuote (as defined below) occurs, the System looks back over the specified time period to determine whether the execution is of sufficient size to trigger the Aggregate Risk Manager. The Aggregate Risk Manager then automatically cancels and removes the Market Maker's Standard quotes and/or Day eQuotes from the Exchange's disseminated quotation in all series of that particular option class until the Market Maker sends a notification to the System of the intent to reengage quoting and submits a new revised quotation in the affected class.

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[24] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term "Market Maker" refers to a "Lead Market Maker," "Primary Lead Market Maker" and "Registered Market Maker" collectively. A Lead Market Maker is a Member registered with the Exchange for the purpose of making markets in securities traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of these Rules with respect to Lead Market Makers. A Primary Lead Market Maker is a Lead Market Maker appointed by the Exchange to act as the Primary Lead Market Maker for the purpose of making markets in securities traded on the Exchange. A Registered Market Maker is a Member registered with the Exchange for the purpose of making markets in securities traded on the Exchange, who is not a Lead Market Maker. *See* Exchange Rule 100.

[4] The Exchange's Board or designated committee appoints one Primary Lead Market Maker and other Market Makers to each options class traded on the Exchange. For a complete description of the Exchange's appointment process, *see* Exchange Rule 602.

[5] A Standard quote is a quote submitted by a Market Maker that cancels and replaces the Market Maker's previous Standard quote, if any. *See* Exchange Rule 517(a)(1).

Any eQuotes[6] other than Day eQuotes[7] present in the market are not cancelled by the Aggregate Risk Manager.

Currently, Exchange Rule 612(a) states that the Market Maker will establish for each option class an AEP that cannot be less than 100%.

First, the proposed amendments to Rule 612(a) would modify the existing rule to allow a Market Maker to establish an AEP at any percentage level for an option class in which such Market Maker is appointed. The Exchange believes that this change will give Market Makers the ability to better manage their risk and help them avoid trading a number of contracts that exceeds the Market Maker's risk tolerance level across multiple series when multiple series are executed in rapid succession.[8]

The purpose of the proposed rule change is to enable individual Market Makers to enhance their risk management for an individual option class or for multiple classes as market conditions warrant, based on their own risk tolerance level and quoting behavior. Market Makers will be able to more precisely customize their risk management within the MIAX System than previously permitted, taking into account such factors as the market conditions both present and anticipated, news that may affect an option class in which they are appointed, a sudden change in the volatility of an option, and other considerations affecting their risk management, without any limitation as to the level of the AEP that will trigger the Aggregate Risk Manager. The proposed rule change will provide greater ability for Market Makers to adapt more exact and precise risk controls based on the Market Maker's risk tolerance levels.

Additionally, the Exchange proposes to amend Exchange Rule 612 to codify the Exchange's existing practice of establishing a default specified time period and a default AEP if such values are not established by a Market Maker. Currently, Exchange Rule 612(a) states that the specified time period cannot exceed 15 seconds. The proposed rule change would provide that the 15-second maximum will apply whether the specified time period is established by the Market Maker or as a default setting.

The proposed rule change codifies that the Exchange will establish a default specified time period and a default AEP ("default settings") on behalf of Market Makers that have not established a specified time period and/or an AEP. The purpose of the default settings is to assist Market Makers in managing their risk in the event that they have not established a specified time period and/or an AEP in a particular appointed option and trading in such appointed option becomes active. For example, a Market Maker might not establish a specified time period or an AEP in an appointed option that has a relatively low average daily volume. If such an appointed option becomes extremely active due to news, world events or overall market changes, the default settings are in place to ensure that the Market Maker's quotations are protected and removed from the Exchange's disseminated quotation when the default setting threshold has been reached. The default settings benefit not only the Market Maker but the marketplace as a whole by enhancing stability and maintaining fair and orderly markets on MIAX when the settings are not established by the Market Maker, and ensure that all Exchange Market Makers are protected by ARM regardless of whether they establish ARM settings on their own. The default settings will be determined by the Exchange on an Exchange-wide basis and announced to Members via Regulatory Circular. The proposed rule change will serve to notify all market participants that the Exchange will establish the default settings for Market Makers and will apply them to all appointed option classes in which a Market Maker has not determined its specified time period or AEP. Any changes to the default settings will also be announced to Members via Regulatory Circular.

The current rule states that the specified time period cannot exceed 15 seconds. This 15-second limitation will apply to the specified time period whether it is established by a Market Maker or set by the Exchange by default; thus the proposed rule change would clarify in the rule text that the specified time period cannot exceed 15 seconds, whether established by the Market Maker or as a default setting. Additionally, although the proposed rule states that the default AEP shall not be less than 100%, this Exchange-established default AEP setting will not limit a Market Maker's ability to establish an AEP of less than or greater than 100%. A Market Maker may establish the AEP for an appointed option class at any level. The Exchange will apply the default settings when a specified time period and/or an AEP has not been established by a Market Maker appointed in an option class. The current default specified time period setting is 1 second. The current default AEP setting is 105%. The Exchange does not propose to change the current default settings in the instant proposed rule change.

The Exchange is proposing two minor technical changes to Exchange Rule 612(a). First, the Rule currently refers to a Market Maker's "assigned" option classes. In order to maintain uniformity within Rule 612, the Exchange proposes to replace the word "assigned" with the word "appointed," as it is used later in the Rule.[9] Additionally, the current Rule states that "[T]he Market Maker will also establish for each option class an Allowable Engagement Percentage . . ." Because of the new codification of the default AEP setting established by the Exchange on behalf of a Market Maker that has not established an AEP in a given appointed class, the Exchange proposes to state that a Market Maker "may" establish an AEP, with the understanding that an AEP will be established by the Exchange on the Market Maker's behalf if not set by the Market Maker.

The Exchange will announce the implementation date of the proposed rule change by Regulatory Circular to be published no later than 60 days following the operative date of the proposed rule. The implementation date will be no later than 60 days following the issuance of the Regulatory Circular.

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[6] An eQuote is a quote with a specific time in force that does not automatically cancel and replace a previous Standard quote or eQuote. An eQuote can be cancelled by the Market Maker at any time, or can be replaced by another eQuote that contains specific instructions to cancel an existing eQuote. *See* Exchange Rule 517(a)(2).

[7] A Day eQuote is a quote submitted by a Market Maker that does not automatically cancel or replace the Market Maker's previous Standard quote or eQuote. Day eQuotes will expire at the close of trading each trading day. *See* Exchange Rule 517(a)(2)(i).

[8] All of a Market Maker's quotes in each option class will be considered firm until such time as the AEP threshold has been equaled or crossed and the Market Maker's quotes are removed by the Aggregate Risk Manager in all series of that option class. Any marketable orders, or quotes that are executable against a Market Maker's disseminated quotation that are received prior to the time the Aggregate Risk Manager is engaged will be automatically executed at the disseminated price up to the Market Maker's disseminated size, regardless of whether such an execution results in executions in excess of the Market Maker's AEP. *See* Exchange Rule 612(c).

[9] *See* Exchange Rule 612, Interpretations and Policies .02(a).

2. Statutory Basis

MIAX believes that its proposed rule change is consistent with Section 6(b) of the Act[10] in general, and furthers the objectives of Section 6(b)(5) of the Act[11] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

Market Makers are obligated to submit continuous two-sided quotations in a certain number of series in their appointed option classes for a certain percentage of each trading session,[12] rendering them vulnerable to risk from unusual market conditions, volatility in specific option classes, and other market events that may cause them to receive multiple, extremely rapid automatic executions before they can adjust their quotations and overall risk exposure in the market. The ability of each Market Maker to adapt their specified time period and AEP to current market conditions is a valuable tool in assisting Market Makers in risk management. The proposed rule change removes impediments to and perfects the mechanism of a free and open market by giving Market Makers the means to establish an AEP that corresponds to their ability to assume the risks inherent in quoting in a marketplace in which executions are instant and quotations must be changed rapidly to account for volatility. This protects investors and the public interest by ensuring that liquidity providers such as Exchange Market Makers are able to quote aggressively within their risk tolerance levels with respect to both price and size, resulting in narrower bid/ask differentials and deeper liquidity on the Exchange, all to the benefit and protection of investors and the public interest.

The proposed default settings further protect investors and the public interest by enhancing the risk management features provided by the Exchange on behalf of Market Makers that have not established a specified time period and/or AEP. The default settings provide Market Makers with risk management tools implemented by the Exchange in the event that a Market Maker has not determined the duration of the specified time period or the AEP for an option class in which the Market Maker is appointed.

Without adequate risk management tools in place on the Exchange, the incentive for Exchange Market Makers to quote aggressively respecting both price and size could be diminished, and could result in a concomitant reduction in the depth and liquidity they provide to the market. Such a result may undermine the quality of the markets that would otherwise be available to customers and other market participants. Accordingly, the Exchange proposes to help Market Makers better manage their risk exposure by giving them the ability to more precisely tailor their AEP to the market conditions present. This should encourage Market Makers to provide additional depth and liquidity to the Exchange's markets, thereby removing impediments to and perfecting the mechanisms of a free and open market and a national market system and, in general, protecting investors and the public interest.

Significantly, the proposed rule change removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest because it codifies and enhances certain features of a risk management tool that is currently available to MIAX Market Makers. The elimination of the minimum AEP threshold requirement simply provides more alternatives to Market Makers in setting their AEP, on a class-by-class basis, without affecting their firm quote obligations. A Market Maker may set its AEP at any level (whether greater than, equal to, or less than 100%) in an appointed option, depending on that Market Maker's evaluation of its own risk tolerance level for that appointed option. The default settings serve to further enhance Market Makers' confidence in the Exchange's ability to assist them in their management of risk, and Market Makers are therefore likely to quote more aggressively in price and size, resulting in potentially narrower bid/ask differentials and deeper liquidity on the Exchange, serving to benefit and protect investors and the public interest.

The proposed rule change also promotes just and equitable principles of trade by codifying the Exchange's current practice of establishing the default settings, thus providing Exchange Market Makers with additional protection in risk management mechanisms on the Exchange. The default settings are proposed to reduce the risks associated with their Market Making obligations. Finally, the proposed rule change is designed to protect investors and the public interest by helping Market Makers prevent executions resulting from activity that exceeds their risk tolerance level under these rules as established by the Exchange and by codifying the Exchange's existing practices concerning default ARM settings.

The Exchange further notes that its proposal regarding minimum and default settings is consistent with rules that are currently in place on other exchanges.

For example, the International Securities Exchange LLC ("ISE") does not impose any minimum AEP or specified time period equivalent on its market makers, but the requirement for ISE market makers to provide these parameters is mandatory. ISE Rule 804(g) requires its market makers to provide parameters by which the Exchange will automatically remove a market maker's quotations. ISE Rule 804(g) differs from the instant proposed rule change in that it has no default percentage or time period settings if not established by the ISE market maker.

BATS BZX Exchange, Inc. ("BATS BZX") Rule 21.16, Risk Monitor Mechanism, states that a single BATS user may configure a single counting program or multiple counting programs to govern its trading activity (*i.e.*, on a per port basis). Just as with ARM, the BATS Risk Monitor Mechanism is based in part on a percentage based trigger (similar to the AEP), measured against the number of contracts executed as a percentage of the number of contracts outstanding within a time period designated by the Exchange ("percentage trigger"). The percentage trigger is calculated similarly to the AEP: The BATS counting program first calculates, for each series of an option class, the percentage of a User's order size in the specified class or a BATS market maker's quote size in the appointed class that is executed on each side of the market, including both displayed and non-displayed size; the counting program then sums the overall series percentages for the entire option class to calculate the percentage trigger. Like the MIAX proposal, BATS BZX Rule 21.16 has no minimum AEP equivalent or minimum specified time period. Unlike the MIAX proposal, BATS BZX does not establish default settings on behalf of its market makers.[13]

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[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] For a complete description of MIAX Market Maker quoting obligations, *see* Exchange Rule 604.

[13] Chicago Board Options Exchange, Inc. ("CBOE") market makers may (but are not required to) establish parameters similar to the specified

The Exchange notes that the proposed rule change will not relieve Exchange Market Makers of their continuous quoting obligations under Exchange Rule 604 and under Reg NMS Rule 602.[14] All of a Market Maker's quotes in each option class will be considered firm until such time as the AEP threshold has been equaled or exceeded and the Market Maker's quotes are removed by the Aggregate Risk Manager in all series of that option class.[15]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

On the contrary, the Exchange believes that the proposed rule change will foster competition by providing Exchange Market Makers with the ability to enhance and specifically customize their use of the Exchange's risk management tools in order to compete for executions and order flow.

As to inter-market competition, the Exchange believes that the proposed rule change should promote competition because it is designed to allow Exchange Market Makers with flexibility to modify their risk exposure in order to protect them from unusual market conditions or events that may increase their exposure in the market.

For all the reasons stated, the Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, and believes the proposed change will in fact enhance competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act[16] and Rule 19b–4(f)(6)[17] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR-MIAX–2016–10 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2016–10. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2016–10 and should be submitted on or before June 8, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–11651 Filed 5–17–16; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice: 9567]

60-Day Notice of Proposed Information Collection: Nonimmigrant Treaty Trader/Investor Application

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up July 18, 2016.

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the Internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering "Docket Number: DOS–2016–0030" in the Search field. Then click the "Comment Now" button and complete the comment form.
- *Email: PRA_BurdenComments@state.gov.* You must include the DS form number, information collection title,

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time period (the CBOE equivalent is a rolling time period in milliseconds) and the AEP. CBOE has no default settings. *See* CBOE Rule 8.18.

[14] 17 CFR 242.602.

[15] *See* Exchange Rule 612(c).

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 17 CFR 200.30–3(a)(12).

and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Taylor Mauck, who may be reached at 202–485–7635 or at *PRA_BurdenComments@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Nonimmigrant Treaty Trader/Investor Application.
- *OMB Control Number:* 1405–0101.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* CA/VO/L/R.
- *Form Number:* DS–156E.
- *Respondents:* Non-Immigrant Visa Applicants.
- *Estimated Number of Respondents:* 48,600.
- *Estimated Number of Responses:* 48,600.
- *Average Time per Response:* 4 Hours.
- *Total Estimated Burden Time:* 194,400 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

Section 101(a)(15)(E) of the Immigration and Nationality Act (INA), 8 U.S.C. 1101(a)(15)(E), includes provisions for the nonimmigrant classification of a national of a country with which the United States maintains an appropriate treaty of commerce and navigation who is coming to the United States to: (i) Carry on substantial trade, including trade in services or technology, principally between the United States and the treaty country; or (ii) develop and direct the operations of an enterprise in which the national has invested, or is actively in the process of investing. Form DS–156E is completed by foreign nationals seeking nonimmigrant treaty trader/investor visas to the United States. The Department will use the DS–156E to elicit information necessary to determine a foreign national's visa eligibility.

Methodology

After completing Form DS–160, Online Nonimmigrant Visa Application, applicants will fill out the DS–156E online, print the form, and submit it in person or via mail.

Dated: April 29, 2016.

Ed Ramotowski,

Deputy Assistant Secretary, Bureau of Consular Affairs, Department of State.

[FR Doc. 2016–11728 Filed 5–17–16; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice: 9566]

Notice of Public Meeting

ACTION: The Department of State will conduct an open meeting at 10:00 a.m. on Wednesday, June 1st, 2016, in Room 2N23–02, United States Coast Guard Headquarters, 2703 Martin Luther King, Jr. Ave. SE., Washington, DC 20593–7213. The primary purpose of the meeting is to prepare for the 103rd Session of the International Maritime Organization's (IMO) Legal Committee to be held at the IMO Headquarters, United Kingdom, June 8–10, 2016.

The agenda items to be considered include:

—HNS Protocol, 2010
—Fair treatment of seafarers in the event of a maritime accident
—Provision of financial security in case of abandoned seafarers
—Technical cooperation activities related to maritime legislation
—Review of the status of conventions and other treaty instruments emanating from the Legal Committee
—Any other business, which may include liability and compensation for transboundary oil pollution arising from offshore exploration and exploitation.

Members of the public may attend this meeting up to the seating capacity of the room. To facilitate the building security process, and to request reasonable accommodation, those who plan to attend should contact the meeting coordinator, Ms. Bronwyn Douglass, by email at *Bronwyn.douglass@uscg.mil,* by phone at (202) 372–3793, or in writing at 2703 Martin Luther King Jr. Ave. SE., Stop 7213, Washington DC 20593–7509 not later than May 27, 2016. Requests made after May 27, 2016 might not be able to be accommodated, and same day requests will not be accommodated due to the building's security process. Please note that due to security considerations, two valid, government issued photo identifications must be presented to gain entrance to Coast Guard Headquarters. It is recommended that attendees arrive to the Headquarters building no later than 30 minutes ahead of the scheduled meeting for the security screening process. The Headquarters building is accessible by taxi and public transportation. Parking in the vicinity of the building is extremely limited and not guaranteed.

In the case of inclement weather where the Federal Government is closed or delayed, a public meeting may be conducted virtually by calling (202) 475–4000 or 1–855–475–2447, Participant code: 887 809 72. The meeting coordinator will confirm whether the virtual public meeting will be utilized. Members of the public can find out whether the Federal Government is delayed or closed by visiting *www.opm.gov/status/.* Additional information regarding this and other IMO public meetings may be found at: *www.uscg.mil/imo.*

Dated: May 10, 2016.

Jonathan W. Burby,

Coast Guard Liaison Officer, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2016–11727 Filed 5–17–16; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice: 9568]

Updated List of Goods and Services Produced by Independent Cuban Entrepreneurs Authorized for Importation

AGENCY: Department of State.

Subagency: Bureau of Economic and Business Affairs.

ACTION: Notice, publication of updated list of goods and services produced by independent Cuban entrepreneurs authorized for importation into the United States.

SUMMARY: On April 22, 2016, the Department of State published on its Web site an updated list of goods and services produced by independent Cuban entrepreneurs whose importation into the United States is authorized by the Department of the Treasury's Cuban Assets Control Regulations ("CACR"). This list updates the version of the list published on February 13, 2015. These changes allow for more engagement with Cuba's private sector through new business opportunities.

DATES: April 22, 2016.

FOR FURTHER INFORMATION CONTACT: Office of Economic Sanctions Policy and Implementation, tel.: 202–647–7489; Office of the Coordinator for Cuban Affairs, tel.: 202–647–9273, Department of State, Washington, DC 20520 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning the List are available from the Department of State's Web site (*http://www.state.gov/e/eb/tfs/spi/cuba/515582/237471.htm*). Additional information about the President's new course on Cuba is also on the Web site (*www.state.gov/p/wha/ci/cu/cuba/*).

Background

On January 16, 2015, the Department of the Treasury's Office of Foreign Assets Control (OFAC) published a final rule in the **Federal Register** (80 FR 2291, Jan. 16, 2015) amending the Cuban Assets Control Regulations (CACR), 31 CFR part 515, to implement the President's December 17, 2014, policy announcement on Cuba. Section 515.582 of the CACR was added to authorize persons subject to U.S. jurisdiction to engage in all transactions, including payments, necessary to import certain goods and services produced by independent Cuban entrepreneurs as determined by the State Department as set forth on the State Department's Section 515.582 List. Empowering the Cuban people and Cuban civil society is central to the Administration's approach to Cuba, which seeks to create new opportunities for Cuba's nascent private sector. The State Department's Section 515.582 List was first published February 13, 2015 on its Web site and went into effect immediately upon publication.

On April 22, 2016, the State Department updated the Section 515.582 List, authorizing persons subject to U.S. jurisdiction to import coffee and additional textiles and textile articles produced by independent Cuban entrepreneurs, in addition to the items previously authorized. The updated List also removes the requirement that imports of authorized goods need to be made directly from Cuba. These changes allow for more engagement with Cuba's private sector through new business opportunities.

The List published on the State Department's Web site on April 22, 2016, replaces in full the version of the List published on February 13, 2015. The List is as follows, and may be updated by the State Department periodically.

U.S. Department of State

Section 515.582 List

Goods and Services Eligible for Importation

In accordance with the policy changes announced by the President on December 17, 2014, to further engage and empower the Cuban people, Section 515.582 of the Cuban Assets Control Regulations (31 CFR part 515—the CACR) authorizes the importation into the United States of certain goods and services produced by independent Cuban entrepreneurs as determined by the State Department as set forth on the Section 515.582 List, below.

Goods

The goods whose import is authorized by Section 515.582 are goods produced by independent Cuban entrepreneurs, as demonstrated by documentary evidence, that are imported into the United States, *except for* goods specified in the following sections/chapters of the Harmonized Tariff Schedule of the United States (HTS):

- Section I: Live Animals; Animal Products
    - All chapters
- Section II: Vegetable Products
    - All chapters, except Chapter 9 heading 0901 (coffee)

**Please note that exporters will be required to prove that they have met all sanitary and phytosanitary standards, including food safety.

- Section III: Animal or Vegetable Fats and Oils and their Cleavage Products; Prepared Edible Fats; Animal or Vegetable Waxes
    - All chapters
- Section IV: Prepared Foodstuffs; Beverages, Spirits, and Vinegar; Tobacco and Manufactured Tobacco Substitutes
    - All chapters
- Section V: Mineral Products
    - All chapters
- Section VI: Products of the Chemical or Allied Industries
    - Chapters 28–32; 35–36, 38
- Section XV: Base Metals and Articles of Base Metal
    - Chapters 72–81
- Section XVI: Machinery and Mechanical Appliances; Electrical Equipment; Parts Thereof; Sound Recorders and Reproducers, Television Image and Sound Recorders and Reproducers, and Parts and Accessories of Such Articles
    - All chapters
- Section XVII: Vehicles, Aircraft, Vessels, and Associated Transportation Equipment
    - All chapters
- Section XIX: Arms and Ammunition; Parts and Accessories Thereof
    - All chapters

This list does not supersede or excuse compliance with any additional requirements in U.S. law or regulation, including the relevant duties as set forth on the HTS.

For travelers importing authorized goods into the United States pursuant to § 515.582 as accompanied baggage, the $400 monetary limit set forth in § 515.560(c)(3) does not apply to such goods, but goods may be subject to applicable duties, fees, and taxes.

Services

The authorized services pursuant to 31 CFR 515.582 are services supplied by an independent Cuban entrepreneur in Cuba, as demonstrated by documentary evidence. Persons subject to U.S. jurisdiction engaging in import transactions involving services supplied by an independent Cuban entrepreneur pursuant to § 515.582 are required to obtain documentary evidence that demonstrates the entrepreneur's independent status, such as a copy of a license to be self-employed issued by the Cuban government or, in the case of an entity, evidence that demonstrates that the entrepreneur is a private entity that is not owned or controlled by the Cuban government. Supply of services must comply with other applicable state and federal laws.

Note 1: All payments in settlement of transactions authorized by § 515.582 should reference this section in order to avoid having them rejected.

Note 2: The authorization in § 515.582 of the CACR does not supersede or excuse compliance with U.S. laws or regulations or any other additional requirements.

Note 3: The Department of State, in consultation with other federal agencies, reserves the right to update this document periodically. Any subsequent updates will take effect when published on the Web page of the Bureau of Economic and Business

Affairs' Office of Sanctions Policy and Implementation (*http://www.state.gov/e/eb/tfs/spi*). Updates will also be published in the **Federal Register**. For further information, please contact the State Department at 202–647–7489.

Note 4: For provisions relating to recordkeeping and reports, see 31 CFR 501.601 and 501.602 and 19 CFR part 163.

With this notice, the Department of State is publishing its April 22, 2016, Section 515.582 List.

Charles H. Rivkin,

Assistant Secretary, Economic and Business Affairs.

[FR Doc. 2016–11730 Filed 5–17–16; 8:45 am]

BILLING CODE 4710–AE–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 35995]

South Carolina Division of Public Railways d/b/a Palmetto Railways—Acquisition Exemption—Hampton & Branchville Railroad Company

South Carolina Division of Public Railways d/b/a Palmetto Railways (Palmetto), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to acquire three connecting line segments that constitute the entire rail line of Hampton & Branchville Railroad Company (H&B), a total distance of approximately 45.77 miles in Colleton and Hampton Counties, S.C. (H&B Line): (1) From a connection with CSX Transportation, Inc., at milepost 0.0 in Hampton to milepost 16.8 at H&B Junction, a distance of 16.8 miles; (2) from the end of track at milepost 462.37 in Lodge through H&B Junction and Stokes to the end of track at milepost 443.18 in Walterboro, a distance of 19.19 miles; and (3) from approximately milepost 447 at Stokes to the end of track at milepost 456.78 in Canadys, a distance of 9.78 miles.[1]

Palmetto has certified that the transaction does not involve any provision or agreement that would limit future interchange with a third-party connecting carrier.

Palmetto states that its projected annual revenues as a result of this transaction will not result in Palmetto's becoming a Class II or Class I rail carrier, but that its projected annual revenues will exceed $5 million. Accordingly, Palmetto is required, at least 60 days before this exemption is to become effective, to send notice of the transaction to the national offices of the labor unions with employees on the affected line, post a copy of the notice at the workplace of the employees on the affected line, and certify to the Board that it has done so. 49 CFR 1150.42(e). Palmetto's verified notice, however, includes a request to waive that requirement. Palmetto states that H&B has not conducted any rail operations in more than three years and does not have any employees, other than its president. Palmetto asserts that providing the 60-day notice would serve no useful purpose because it is merely acquiring the Line to prevent abandonment. Palmetto's waiver request will be addressed in a separate decision.

Palmetto states that it expects to consummate the transaction on or after August 5, 2016.[2] The Board will establish in the decision on the waiver request the earliest date this transaction may be consummated.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than May 25, 2016.

An original and 10 copies of all pleadings, referring to Docket No. FD 35995, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Thomas J. Litwiler, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 920, Chicago, IL 60606.

Board decisions and notices are available on our Web site at "*WWW.STB.DOT.GOV*".

Decided: May 13, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2016–11721 Filed 5–17–16; 8:45 am]

BILLING CODE 4915–01–P

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[1] Palmetto states that no rail service has been provided on the H&B Line since H&B's final customer ceased rail shipments in December 2012. Palmetto also states that the stub track between H&B Junction and Lodge has not been in service since 1986, and the stub track between Stokes and Walterboro has not been in service since 1989. According to Palmetto, certain trackage on both stubs has been removed, but neither segment has been abandoned.

[2] Palmetto states that H&B and Palmetto have agreed upon the terms of an Asset Purchase and Sale Agreement providing for Palmetto's acquisition of all of H&B's right, title, and interest in the H&B Line. According to Palmetto, the Agreement will be fully executed after Palmetto receives the necessary state agency approvals. Palmetto states that it will concurrently execute a Loan and Security Agreement with Colleton County Intermodal Corporation (CCIC) and Colleton County providing for CCIC's financing of the acquisition transaction through the issuance of economic development revenue bonds.

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Determination Regarding Waiver of Discriminatory Purchasing Requirements With Respect to Goods and Services of Ukraine

AGENCY: Office of the United States Trade Representative.

ACTION: Determination regarding waiver of discriminatory purchasing requirements under the Trade Agreements Act of 1979.

DATES: Effective May 18, 2016.

FOR FURTHER INFORMATION CONTACT: Scott Pietan, Director of International Procurement Policy, Office of the United States Trade Representative, (202) 395–9646.

SUPPLEMENTARY INFORMATION: On November 11, 2015, the WTO Committee on Government Procurement approved the accession of Ukraine to the World Trade Organization ("WTO") Agreement on Government Procurement ("GPA"). Ukraine submitted its instrument of accession to the Secretary-General of the WTO on April 18, 2016. The GPA will enter into force for Ukraine on May 18, 2016. The United States, which is also a party to the GPA, has agreed to waive discriminatory purchasing requirements for eligible products and suppliers of Ukraine beginning on May 18, 2016. Section 1–201 of Executive Order 12260 of December 31, 1980 delegated the functions of the President under sections 301 and 302 of the Trade Agreements Act of 1979 ("the Trade Agreements Act") (19 U.S.C. 2511, 2512) to the United States Trade Representative.

Determination: In conformity with sections 301 and 302 of the Trade Agreements Act, and in order to carry out U.S. obligations under the GPA, I hereby determine that:

1. Ukraine has become a party to the GPA and will provide appropriate reciprocal competitive government procurement opportunities to United States products and services and suppliers of such products and services. In accordance with section 301(b)(1) of the Trade Agreements Act, Ukraine is so designated for purposes of section 301(a) of the Trade Agreements Act.

2. Accordingly, beginning on May 18, 2016, with respect to eligible products (namely, those goods and services covered under the GPA for procurement by the United States) of Ukraine and suppliers of such products, the application of any law, regulation, procedure, or practice regarding government procurement that would, if applied to such products and suppliers, result in treatment less favorable than that accorded—

(A) to United States products and suppliers of such products, or

(B) to eligible products of another foreign country or instrumentality which is a party to the GPA and suppliers of such products, shall be waived. This waiver shall be applied by all entities listed in United States Annexes 1 and 3 of GPA Appendix 1.

3. The Trade Representative may modify or withdraw the designation in paragraph 1 and the waiver in paragraph 2.

Michael B.G. Froman,

United States Trade Representative.

[FR Doc. 2016–11669 Filed 5–17–16; 8:45 am]

BILLING CODE 3290–F6–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Eighteenth Meeting: RTCA NextGen Advisory Committee (NAC)

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Notice of Eighteenth RTCA NextGen Advisory Committee Meeting.

SUMMARY: The FAA is issuing this notice to advise the public of the Eighteenth RTCA NextGen Advisory Committee meeting.

DATES: The meeting will be held June 17, 2016 from 9:00 a.m.–3:00 p.m.

ADDRESSES: The meeting will be held at The Boeing Company, 929 Long Bridge Drive, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC, 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org* or Andy Cebula, NAC Secretary, RTCA, Inc., *acebula@rtca.org,* (202) 330–0652.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of RTCA NextGen Advisory Committee. The agenda will include the following:

Friday, June 17, 2016 (9:00 a.m. and 3:00 p.m. EDT)

1. Opening of Meeting/Introduction of NAC Members—Chairman Richard Anderson
2. Official Statement of Designated Federal Official—The Honorable Mike Whitaker, FAA Deputy Administrator & Chief NextGen Officer
3. Review and Approval of February 25, 2016 Meeting Summary
4. Chairman's Report—Chairman Anderson
5. FAA Report—Mr. Whitaker
6. Airline C/N/S Fleet Plans—JetBlue Equipage
7. ADS–B Update
8. NextGen Integration Working Group (NIWG): Exec Team Update and NIWG Reports & Plans: DataComm, Multiple Runway Operations, Surface & Data Sharing, Performance Based Navigation (PBN)
9. PBN Implementation
10. Joint Analysis Team—Wake ReCat Assessment Recommendation
11. PBN Blueprint Community Outreach Task Group—Recommendation
12. PBN Time, Speed, Spacing Task Group—Interim Report
13. Summary of meeting and next steps
14. Closing Comments—DFO and NAC Chairman
15. Other business
16. Adjourn

Although the NAC meeting is open to the public, the meeting location has security protocols that require advanced registration. Please email *bteel@rtca.org* with name, company and country of citizenship to pre-register. Attendance is limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Plenary information will be provided upon request. Persons who wish to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on May 13, 2016.

Latasha Robinson,

Management & Program Analyst, NextGen, Enterprise Support Services Division, Federal Aviation Administration.

[FR Doc. 2016–11715 Filed 5–17–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2000–7257, Notice No. 82]

Railroad Safety Advisory Committee; Charter Renewal

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation (DOT).

ACTION: Announcement of charter renewal of the Railroad Safety Advisory Committee (RSAC).

SUMMARY: FRA announces the charter renewal of the RSAC, a Federal Advisory Committee that develops railroad safety regulations through a consensus process. This charter renewal will take effect on May 16, 2016, and will expire after 2 years.

FOR FURTHER INFORMATION CONTACT: Mr. Larry Woolverton, RSAC Designated Federal Officer/Administrative Officer, FRA, 1200 New Jersey Avenue SE., Mailstop 25, Washington, DC 20590, (202) 493–6212; or Mr. Robert Lauby, Associate Administrator for Railroad Safety/Chief Safety Officer, FRA, 1200 New Jersey Avenue SE., Mailstop 25, Washington, DC 20590, (202) 493–6474.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), FRA is giving notice of the charter renewal for the RSAC. The RSAC was established to provide advice and recommendations to FRA on railroad safety matters. The RSAC is composed of 63 voting representatives from 37 member organizations, representing various rail industry perspectives. In addition, there are nonvoting advisory representatives from the agencies with railroad safety regulatory responsibility in Canada and Mexico, the National Transportation Safety Board, the Transportation Safety Administration, and the Federal Transit Administration. The diversity of the committee ensures the requisite range of views and expertise necessary to discharge its responsibilities. See the RSAC Web site for details on pending tasks at: *http://rsac.fra.dot.gov/.* Please refer to the notice published in the **Federal Register** on March 11, 1996, 61 FR 9740, for additional information about the RSAC.

Issued in Washington, DC, on May 10, 2016.

Robert C. Lauby,

Associate Administrator for Railroad Safety Chief Safety Officer.

[FR Doc. 2016–11673 Filed 5–17–16; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0049]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel AVALANCHE; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before June 17, 2016.

ADDRESSES: Comments should refer to docket number MARAD–2016–0049. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel AVALANCHE is:

Intended Commercial Use of Vessel: 6-pack charters

Geographic Region: "New England, Rhode Island, Connecticut, New York, Massachusetts, Maine, Maryland, New Jersey and Delaware."

The complete application is given in DOT docket MARAD–2016–0049 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: May 10, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–11722 Filed 5–17–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0047]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel TRUE NORTH II; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before June 17, 2016.

ADDRESSES: Comments should refer to docket number MARAD–2016–0047. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel TRUE NORTH II is:

Intended Commercial Use of Vessel: "Whale watching and charter fishing"

Geographic Region: "ALASKA (excluding waters in Southeastern Alaska and waters north of a line between Gore Point to Cape Suckling [including the North Gulf Coast and Prince William Sound])".

The complete application is given in DOT docket MARAD–2016–0047 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: May 10, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–11719 Filed 5–17–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0048]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel COOL BEANS III; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before June 17, 2016.

ADDRESSES: Comments should refer to docket number MARAD–2016 0048. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel COOL BEANS III is:

Intended Commercial Use of Vessel: "SIGHTSEEING EXCURSION IN NAPLES/MAROC ISLAND FLORIDA"

Geographic Region: "FLORIDA"

The complete application is given in DOT docket MARAD–2016–0048 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: May 10, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–11716 Filed 5–17–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0046]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel GRACE; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before June 17, 2016.

ADDRESSES: Comments should refer to docket number MARAD–2016–0046. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.Carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel GRACE is:

Intended Commercial Use of Vessel: Six pack charters

Geographic Region: Maryland, Virginia

The complete application is given in DOT docket MARAD–2016–0046 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: May 10, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–11725 Filed 5–17–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0050]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel FEEL THE MAGIC; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before June 17, 2016.

ADDRESSES: Comments should refer to docket number MARAD–2016–0050. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel FEEL THE MAGIC is:

Intended Commercial Use of Vessel: "Crewed Yacht Charter"

Geographic Region: "Puerto Rico, Florida"

The complete application is given in DOT docket MARAD–2016–0050 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: May 10, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–11714 Filed 5–17–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[DOT Docket No. NHTSA –2016–0036]

Guidelines for the Safe Deployment and Operation of Automated Vehicle Safety Technologies.

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Extension of comment period for proposed Guidelines for the Safe Deployment and Operation of Automated Vehicle Safety Technologies

SUMMARY: This document extends the comment period on planned guidelines for the safe deployment and operation of automated vehicles. The intent of the operational guidance is to encourage innovative and safe deployment of automated vehicle technologies. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral comments and supporting information presented at the public meetings. The comment due date was May 9, 2016.

Comments continue to come in and requests have been made to extend the period to provide comments on this important topic. This document grants that request and extends the comment due date for the planned Guidelines to May 31, 2016.

DATES: The due date for comments on DOT Docket No. NHTSA–2016–0036 is extended to May 31, 2016

ADDRESSES: Please submit all written comments no later than May 31, 2016, by any of the following methods:

- *Federal Rulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal Holidays.
- *Fax:* 202–366–1767.

Instructions: All submissions must include the agency name and docket number. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act discussion below.

Docket: For access to the docket go to *http://www.regulations.gov* at any time or to 1200 New Jersey Avenue SE., West Building, Ground Floor, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays. Telephone: 202–366–9826.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or you may visit *http://www.regulations.gov/privacy.html.*

Confidential Business Information: If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information to the Chief Counsel, NHTSA, at the address given under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit two copies, from which you have deleted the claimed confidential business information, to Docket Management at the address given above. When you send a comment containing information claimed to be confidential business information, you should submit a cover letter setting forth the information specified in our confidential business information regulation (49 CFR part 512).

SUPPLEMENTARY INFORMATION:

Background

DOT recently announced a series of actions to remove potential roadblocks to the integration of innovative automotive technology. As part of this effort, the Department announced several milestones for 2016, including development of guidance on the safe deployment and operation of automated vehicles.

NHTSA held two public meetings where participants could address a panel on the topic of guidance on the safe deployment and operation of automated vehicles. The meetings were held in Washington, DC on April 8, 2016, and in Stanford, CA on April 27, 2016.

Public Meeting Topics

During the public meetings NHTSA sought input on the following topics:

1. *Evaluation and testing of scenarios the AV system should detect and correctly operate in:* Within the AV system's operating envelope, consider how to identify the scenarios that could be encountered by the AV system (*e.g.,* behavioral competencies/normal driving, pre-crash scenarios, etc.) and what design and evaluation (testing) processes and methods are needed to ensure that the vehicle can detect and appropriately react to these scenarios. Consider whether third party testing is appropriate for validating test results.

2. *Detection and communication of operational boundaries:* If there are limitations on where AV technology will operate—what methods should the AV technology use to sense when it is reaching the operational domain limit and how should that be communicated to the driver?

3. *Environmental operation and sensing:* Consider what environmental conditions AV systems will likely operate in. For environmental conditions in which AV systems are not designed to operate, discuss methods used to detect these conditions.

4. *Driver transitioning to/from AV operating mode:* For AV systems that rely on transferring vehicle operation back to the driver, discuss approaches to (a) ensuring safe transitioning back to a fully capable non-impaired driver (*e.g.,* geo-fencing, adverse weather) and (b) how non-optimal driver behavior (*e.g.,* decision errors, erratic behavior, driver impairment) will be addressed by the AV system.

5. *AV for persons with disabilities:* Consider the unique needs of people with different types of disabilities in the design, development, and policy setting for self-driving cars and related automation.

6. *Data:* Consider data recording capabilities of system(s) necessary to monitor the correct operation of the AV system, and what are appropriate triggers (crash, near crash, etc.) to determine system operational status or possible malfunction of the system. Also consider how recorded data could be accessed and by whom. During the testing phase, consider what data should be made public for further analysis and understanding.

7. *Crash avoidance capability:* Consider the capabilities of AV systems with respect to detecting roadway hazards (other vehicles, pedestrians, animals, etc.) such that common crash scenarios involving these hazards (control loss, crossing paths head-on, etc.) can be detected and either avoided or mitigated.

8. *Electronics systems safety:* Consider methods and potential documentation that could be produced with respect to functional safety and cybersecurity.

9. *Non-passenger AVs:* Consider differences between AVs designed for delivery of goods and products that are not intended to have a human operator or potentially even human passengers.

10. *Aspects of AV technology that may not be suitable or ready for guidelines:* For these areas, information would be useful on alternative approaches to assure safety.

11. *Identification of industry voluntary standards, best practices, etc.,* related to automated vehicle operation.

12. *Information AVs may need to communicate to pedestrians and other vehicles (manual or automated) just as a driver would.* Consider situations such as pedestrians crossing a travel lane in a parking lot and how this communication should be accomplished.

13. *Conditions in which AVs may need to be able to identify and communicate to a central location or authority that a problem has occurred.* Consider situations where passengers may be delivered to their destination but a medical problem or potential incapacitation enroute may potentially suggest considerations for vehicle capabilities that could handle such cases.

14. *Operation of an AV with open safety recall:* Consider if automated vehicles should be allowed to operate in automated mode in cases when there is an open safety recall on that vehicle or if automated functions should be restrained until recall repairs are completed (perhaps reversion to manual driving when possible). Consider if AVs with open recalls should be allowed to operate on public roads at all, and if so, under what conditions.

15. *Other topics needed for operational guidance:* Other topics that would be beneficial to address in an operational guidance document to facilitate innovation and safe deployment of these systems on public roadways.

Issued in Washington, DC, under authority delegated by 49 CFR 1.95.

Nathaniel Beuse,

Associate Administrator for Vehicle Safety Research.

[FR Doc. 2016–11635 Filed 5–17–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Sanctions Action Pursuant to Executive Order 13726 of April 19, 2016, "Blocking Property and Suspending Entry Into the United States of Persons Contributing to the Situation In Libya."

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the name of one individual whose property and interests in property are blocked pursuant to Executive Order 13726 of April 19, 2016, "Blocking Property and Suspending Entry into the United States of Persons Contributing to the Situation in Libya," and whose name has been added to OFAC's list of Specially Designated Nationals and Blocked Persons (SDN List).

DATES: OFAC's actions described in this notice were effective May 13, 2016.

FOR FURTHER INFORMATION CONTACT: Associate Director for Global Targeting, tel.: 202/622–2420, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202/622–2490, Assistant Director for Licensing, tel.: 202/622–2480, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202/622–2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

The SDN List and additional information concerning OFAC sanctions programs are available from OFAC's Web site (*www.treasury.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs is also available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Notice of OFAC Actions

On May 13, 2016, OFAC blocked the property and interests in property of the following individual pursuant to Executive Order 13726 of April 19, 2016, "Blocking Property and Suspending Entry into the United States of Persons Contributing to the Situation in Libya:"

ESSA, Agila Saleh (a.k.a. GWAIDER, Ageela Salah Issa; a.k.a. GWAIDER, Agila Saleh Issa; a.k.a. ISSA, Aguila Saleh; a.k.a. QUYDIR, Aqilah Salih; a.k.a. SALEH, Aqilah); DOB 01 Jun 1942; POB Elgubba, Libya; nationality Libya; Passport D001001 (Libya) issued 22 Jan 2015 expires 22 Jan 2017; President and Speaker of the Libyan House of Representatives (individual) [LIBYA3].

Dated: May 13, 2016.

Andrea M. Gacki,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2016–11697 Filed 5–17–16; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Supplemental Information for 57 Individuals and 42 Entities Designated Pursuant to Executive Orders 12947, 13224, and/or 13582

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control (OFAC) is publishing supplemental information on the List of Specially Designated Nationals and Blocked Persons (SDN List) for 57 individuals and 42 entities whose property and interests in property are blocked pursuant to one or more of the following authorities: Executive Order 13224, "Blocking Property and Prohibiting Transactions with Persons who Commit, Threaten to Commit, or Support Terrorism;" Executive Order 12947, "Prohibiting Transactions With Terrorists Who Threaten To Disrupt the Middle East Peace Process;" and Executive Order 13582, "Blocking Property of the Government of Syria and Prohibiting Certain Transactions With Respect to Syria." The SDN List entry for each of these individuals and entities has been amended to include the language "Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations."

DATES: The amendments to the SDN List described in this notice were published on April 15 and May 11, 2016.

FOR FURTHER INFORMATION CONTACT: Associate Director for Global Targeting, tel.: 202/622–2420, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202/622–2490, Assistant Director for Licensing, tel.: 202/622–2480, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202/622–2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

The SDN List and additional information concerning OFAC sanctions programs are available from OFAC's Web site (*www.treas.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs is also available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Notice of OFAC Actions

On April 15 and May 11, 2016, OFAC amended the SDN List to include supplemental information for 57 individuals and 42 entities whose property and interests in property are blocked pursuant to one or more of the following authorities: Executive Order 13224, "Blocking Property and Prohibiting Transactions with Persons who Commit, Threaten to Commit, or Support Terrorism;" Executive Order 12947, "Prohibiting Transactions With Terrorists Who Threaten To Disrupt the Middle East Peace Process;" and Executive Order 13582, "Blocking Property of the Government of Syria and Prohibiting Certain Transactions With Respect to Syria." As amended, the SDN List entries for the individuals and entities are as follows:

Individuals

1. ABDALLAH, Muhammad Yusif, Avenue Presidente Juscelino Kubistcheck 338, Apartment 1802, Center, Foz do Iguacu, Brazil; Avenue Presidente Juscelino Kubistcheck 133, Apartment 102, Center, Foz do Iguacu, Brazil; DOB 15 Jun 1952; POB Khalia, Lebanon; citizen Lebanon; alt. citizen Paraguay; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Cedula No. 1110775 (Paraguay); Passport 670317 (Lebanon); alt. Passport 137532 (Paraguay) (individual) [SDGT].
2. ALIQ, Qasim (a.k.a. ALEIK, Kassem; a.k.a. 'ALIQ, Hajj Qasim; a.k.a. 'ALIQ, Qasem; a.k.a. 'ULAYQ, Qasim); DOB 1956; POB Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].
3. AL-MUSAWI, Ali Mussa Daqduq (a.k.a. 'ABD AL-YUNIS, Hamid Majid; a.k.a. AL-LAMI, Hamid Muhammad; a.k.a. AL-MASUI, Husayn Muhammad Jabur; a.k.a. AL-MUSAWI, Hamid Muhammad Daqduq; a.k.a. AL-MUSAWI, Hamid Muhammad Jabur; a.k.a. AL-MUSUI, Hamid Muhammad Jabur; a.k.a. DAQDUQ, Ali Mussa; a.k.a. JABUR AL-LAMI, Hamid Muhammad); DOB 01 Sep 1969; alt. DOB 31 Dec 1971; alt. DOB 09 Aug 1971; alt. DOB 09 Sep 1970; alt. DOB 09 Aug 1969; alt. DOB 05 Mar 1972; POB Beirut, Lebanon; alt. POB Al-Karradah, Baghdad, Iraq; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah

Financial Sanctions Regulations (individual) [SDGT].

4. AL-QUBAYSI, Abd-al-Munim (a.k.a. KOBEISSI, Abd Al Menhem; a.k.a. KOBEISSI, Abdel Menhem; a.k.a. KOBEISSI, Abdul Menhem; a.k.a. KOBEISSY, Abdul Menhem; a.k.a. KUBAYSY, Abd Al Munhim; a.k.a. QUBAYSI, Abd Al Menhem); DOB 01 Jan 1964; alt. DOB 1961; POB Beirut, Lebanon; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport RL 1622378 (Lebanon) (individual) [SDGT].

5. AL-SHAMI, Ahmad; DOB 1965; POB Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

6. AL-SHAMI, Husayn (a.k.a. AL-SHAMI, Haj Husayn; a.k.a. AL-SHAMY, Husayn; a.k.a. ASHAMI, Husayn; a.k.a. SHAIMI, Husayn; a.k.a. SHAMAI, Husayn; a.k.a. SHAMY, Husayn), Lebanon; DOB 1948; alt. DOB 1954; alt. DOB 1960; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

7. AL-WATFA, Ali Ibrahim (a.k.a. AL-WAFA, Ali Ibrahim; a.k.a. AL-WAFA, Alie Ibrahim; a.k.a. AL-WATFA, Alie Ibrahim; a.k.a. IBRAHIM, Al Hajj Alie), 26 Malama Thomas Street, Freetown, Sierra Leone; DOB 1969; POB Al Qalamun, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

8. AMHAZ, Kamel Mohamad (a.k.a. AL-AMHAZ, Kamel; a.k.a. AMHAZ, Kamel; a.k.a. AMHAZ, Kamel Mohamed; a.k.a. AMHAZ, Kamil), 5th Floor, Ghadir Building, Kods Street, Haret Hreik, Baabda, Lebanon; Ghadir, 5th Floor, Safarat, Bir Hassan, Jenah, Lebanon; Ghadir 5th Floor, Embassies Street, Bir Hasan, Lebanon; Dallas Center, Saida Old Street, Chiah, Baabda, Lebanon; DOB 04 Aug 1973; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport RL2244333 (Lebanon); Identification Number 61 Niha El-Mehfara; President and Chief Executive Officer, Stars Group Holding (individual) [SDGT].

9. AMHAZ, Issam Mohamad (a.k.a. AMHAZ, 'Isam; a.k.a. AMHAZ, Issam Mohamed), Ghadir, 5th Floor, Safarat, Bir Hassan, Jenah, Lebanon; Issam Mohamad Amhaz Property, Ambassades (Safarate), Bir Hassan Area, Ghobeiri, Baabda, Lebanon; DOB 04 Mar 1967; POB Baalbek, Lebanon; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport RL0000199 (Lebanon); Identification Number 61 Nabha; Chairman, Stars Group Holding; General Manager, Teleserveplus (individual) [SDGT].

10. AQIL, Ibrahim (a.k.a. AKIEL, Ibrahim Mohamed; a.k.a. AKIL, Ibrahim Mohamed); DOB 24 Dec 1962; alt. DOB 01 Jan 1962; POB Bidnayil, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SYRIA] (Linked To: HIZBALLAH).

11. ATRIS, Hussein (a.k.a. HUSSEIN, Atris); DOB 11 Nov 1964; POB Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

12. ATWA, Ali (a.k.a. BOUSLIM, Ammar Mansour; a.k.a. SALIM, Hassan Rostom), Lebanon; DOB 1960; POB Lebanon; citizen Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

13. BADR AL DIN, Mustafa (a.k.a. AL FIQAR, Dhu; a.k.a. BADREDDINE, Mustafa Amine; a.k.a. BADREDDINE, Mustafa Youssef; a.k.a. ISSA, Sami; a.k.a. SAAB, Elias Fouad; a.k.a. SA'B, Ilyas), Beirut, Lebanon; DOB 06 Apr 1961; POB Al-Ghobeiry, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT] [SYRIA] (Linked To: HIZBALLAH).

14. BARAKAT, Hatim Ahmad (a.k.a. BARAKAT, Hatam Ahmad; a.k.a. BARAKAT, Hatem Ahmad; a.k.a. BARAKAT, Hattem Ahmad; a.k.a. BARAKAT, Hotem Ahmad); DOB 25 Sep 1961; POB Mousaitbe, Lebanon; alt. citizen Lebanon; alt. citizen Paraguay; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport 183319 (Paraguay); alt. Passport 148842 (Paraguay); alt. Passport 106318 (Paraguay); Identification Number 2.194.575 (Paraguay); alt. Identification Number 2.194.975 (Paraguay) (individual) [SDGT].

15. BARAKAT, Mohammad Fayez; DOB 11 Mar 1969; POB Rubtlatine, Lebanon; alt. citizen Lebanon; alt. citizen Paraguay; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Identification Number 2.121.948 (Paraguay) (individual) [SDGT].

16. BARAKAT, Assad Ahmad (a.k.a. BARAKAT, Assaad Ahmad; a.k.a. BARAKAT, Assad; a.k.a. BARAKAT, Assad Ahmed Muhammad; a.k.a. BARAKAT, Assad Hassan; a.k.a. BARAKAT, Jach Assad Ahmad; a.k.a. "HAJJ AS'AD AHMAD"), Rue Taroba 1005, Beatriz Menez Building, Foz do Iguacu, Brazil; Rua Rio Branco Lote 682, Quadra 13, Foz do Iguacu, Brazil; Rua Xavier Da Silva 535, Edificio Martin Terro, Apartment 301, Foz do Iguacu, Brazil; Rua Silva Jardim 290, Foz do Iguacu, Brazil; Arrecife Apartment Building, Iquique, Chile; Apartment 111, Panorama Building, Iquique, Chile; Piribebuy Y A. Jara, Ciudad del Este, Paraguay; DOB 25 Mar 1967; POB Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

17. CHARARA, Ali Youssef (a.k.a. SHARARA, Ali Youssef; a.k.a. SHARARA, 'Ali Yusuf), Ghobeiry Center, Mcharrafieh, Beirut, Lebanon; Verdun 732 Center, 17th Floor, Verdun, Rachid Karameh Street, Beirut, Lebanon; Al-Ahlam, 4th Floor, Embassies Street, Bir Hassan, Beirut, Lebanon; DOB 25 Sep 1968; POB Sidon, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Gender Male (individual) [SDGT] (Linked To: HIZBALLAH).

18. CHEHADE, Ali Ahmad (a.k.a. CHEADE, Ali; a.k.a. CHEHADE, Abou Hassan Ali; a.k.a. JAWAD, Abou Hassan; a.k.a. JAWAD, Abu Hassan; a.k.a. SHIHADI, Ali), Abidjan, Cote d Ivoire; DOB 05 Jan 1961; POB Ansarie, Lebanon; citizen Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport RL0516070 (Lebanon) (individual) [SDGT].

19. CHERRI, Adel Mohamad (a.k.a. CHERRI, Adel Mohammad; a.k.a. SHIRRI, 'Adil), Suite 15A, Mingshang GE Shenganghao Yuan Building, Bao An Nan Road, Luohu District, Shenzhen, Guangdong, China; 1/F, Bei Fang Building, Shennan Zhong Road, Shenzhen, Guangdong, China; Flat/Room 1610, Nan Fung Tower, 173 Des Voeux Road Central, Hong Kong; Cherri Building, Main Street, Beer Al Salasel, Kherbet Selem, Nabatieh, Lebanon; DOB 03 Oct 1963; POB Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Gender Male; Passport RL2566575 (Lebanon) expires 03 Jul 2018 (individual) [SDGT] (Linked To: HIZBALLAH).

20. FADLALLAH, Shaykh Muhammad Husayn; DOB 1938; alt. DOB 1936; POB Najf Al Ashraf (Najaf), Iraq; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Leading Ideological Figure of HIZBALLAH (individual) [SDT].

21. FARAH, Meliad (a.k.a. "HUSSEIN"; a.k.a. "HUSSEIN, Hussein"); DOB 05 Nov 1980; citizen Australia; alt. citizen Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

22. FA'UR, Husayn Ali (a.k.a. FAOUR, Housein Ali); DOB 1966; POB Al-Khayam, Lebanon; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Gender Male (individual) [SDGT] (Linked To: HIZBALLAH).

23. FAWAZ, Fouzi Reda Darwish (a.k.a. DARWISH-FAWAZ, Fawzy Reda; a.k.a. DARWISH-FAWAZ, Fouzi Reda; a.k.a. FAWAZ, Fawzi Reda; a.k.a. FAWAZ, Fawzy; a.k.a. FAWAZ, Fowzy; a.k.a. FAWWAZ, Fawzi); DOB 12 Feb 1968; alt. DOB 24 Mar 1973; POB Jwaya, Lebanon; alt. POB Sierra Leone; citizen Lebanon; alt. citizen Nigeria; alt. citizen Sierra Leone; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport 0107516 (Lebanon); alt. Passport 0258649 (individual) [SDGT] (Linked To: HIZBALLAH).

24. FAWAZ, Mustapha Reda Darwish (a.k.a. DARWISH-FAWAZ, Moustafa Reda; a.k.a. FAWAZ, Mostafa Reda Darwich; a.k.a. FAWAZ, Moustapha; a.k.a. FAWAZ, Mustafa; a.k.a. FAWAZ, Mustafa Darwish; a.k.a. FAWAZ, Mustapha; a.k.a. FAWAZ,

Mustapha Rhoda Darwich; a.k.a. FAWAZ, Mustapha Rida Darwich; a.k.a. FAWWAZ, Mustafa), Flat 4, Blantyre Street, Behind Amigo Supermarket, Wuse II, Abuja, Nigeria; 3 Gaya Road, Kano, Nigeria; DOB 25 Jun 1964; alt. DOB 10 Sep 1964; POB Jwaya, Lebanon; alt. POB Koidu Town, Sierra Leone; citizen Lebanon; alt. citizen Nigeria; alt. citizen Sierra Leone; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Gender Male; Passport RL 2101602 (Lebanon); alt. Passport RL 0148105 (Lebanon); alt. Passport 0168459 (Sierra Leone); alt. Passport 0257909 (Sierra Leone); SSN 418–15–2837 (United States) (individual) [SDGT] (Linked To: HIZBALLAH).

25. FAWAZ, Abbas Loutfe (a.k.a. FAWWAZ, 'Abbas Abu-Ahmad; a.k.a. FOUAZ, Abbas), Dakar, Senegal; DOB 07 Aug 1978; POB Jwaya, Lebanon; alt. POB Dakar, Senegal; citizen Lebanon; alt. citizen Senegal; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Personal ID Card 096574S (Senegal) (individual) [SDGT].

26. FAYAD, Saleh Mahmoud (a.k.a. FAYYAD, Saleh Mahmud); DOB 20 Oct 1972; POB Al-Taybe, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

27. FAYAD, Sobhi Mahmoud (a.k.a. FAYAD, Soubi Mamout; a.k.a. FAYADH, Sobhi Mahmoud; a.k.a. FAYYAD, Subhi Mahmud), 315, Piso 3, Galeria Page, Ciudad del Este, Paraguay; DOB 20 Aug 1965; POB Al-Taybe, Lebanon; alt. citizen Lebanon; alt. citizen Paraguay; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport 1035562 (Paraguay); alt. Passport 220705 (Paraguay); alt. Passport 189103 (Paraguay); alt. Passport 142517 (Paraguay); alt. Passport 002301585 (Paraguay) (individual) [SDGT].

28. HAMIYAH, Talal (a.k.a. HAMIYAH, Talal Husni; a.k.a. MEZERANI, Ismat); DOB 27 Nov 1952; alt. DOB 18 Mar 1960; alt. DOB 05 Mar 1958; alt. DOB 08 Dec 1958; POB Tarayya, Lebanon; alt. POB Sojad, Lebanon; nationality Lebanon; citizen Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

29. HARB, Khalil Yusif (a.k.a. AHMAD, Sayyid; a.k.a. HARB, Hajj Ya'taqad Khalil; a.k.a. HARB, Khalil Yusuf; a.k.a. HARB, Mustafa Khalil; a.k.a. MUSTAFA, Abu); DOB 09 Oct 1958; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

30. HASSAN, Hassan el-Hajj (a.k.a. HASSAN, Hassan El Hajj); DOB 22 Mar 1988; citizen Canada; alt. citizen Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

31. IBRAHIM, Ayman (a.k.a. IBRAHIM, Ayman Ahmad); DOB 01 Apr 1979; POB 'Adlun, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; General Manager, Unique Stars Mobile Phones LLC (individual) [SDGT] (Linked To: UNIQUE STARS MOBILE PHONES LLC).

32. IZZ-AL-DIN, Hasan (a.k.a. SALWWAN, Samir; a.k.a. "GARBAYA, AHMED"; a.k.a. "SA-ID"), Lebanon; DOB 1963; POB Lebanon; citizen Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

33. KAN'AN, Fawzi Mustafa (a.k.a. CANAAN, Fazi; a.k.a. CAN'AN, Faouzi; a.k.a. GANAN, Fauzi; a.k.a. KANAAN, Fauzi; a.k.a. KANAAN, Maustaf Fawzi (Faouzi); a.k.a. KAN'AN, Fawzi; a.k.a. KANAN, Fouzi), Calle 2, Residencias Cosmos, Fifth Floor, Apartment 5D, La Urbina, Caracas, Venezuela; Esquina Bucare, Building 703, Second Floor, Apartment 20, Caracas, Venezuela; DOB 07 Jun 1943; alt. DOB Feb 1943; alt. DOB 01 Jun 1943; POB Lebanon; alt. POB Betechelida, Lebanon; alt. POB Baalbeck, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport 0877677 (Venezuela); National ID No. V–6.919.272 (Venezuela) (individual) [SDGT].

34. KAWTHARANI, Muhammad (a.k.a. AL-KAWTHARANI, Jafar; a.k.a. AL-KAWTHARANI, Muhammad; a.k.a. KAWTARANI, Muhammad; a.k.a. KAWTHARANI, Mohammad); DOB 1945; alt. DOB 1959; alt. DOB 1961; POB Najaf, Iraq; nationality Lebanon; alt. nationality Iraq; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

35. KAZAN, Ali Muhammad (a.k.a. KASSAN, Ali Mohamad; a.k.a. QAZAN, Ali Mohamad), Avenue Taroba, 1005 Edificio Beatriz Mendes, Apt 1704, Foz do Iguacu, Brazil; DOB 19 Dec 1967; POB Taibe, Lebanon; alt. citizen Lebanon; alt. citizen Paraguay; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport 0089044 (Lebanon) (individual) [SDGT].

36. KHALIFEH, Hanna Elias (a.k.a. KHALIFAH, Hanna; a.k.a. KHALIFE, Hanna), Midan Street, Mazraat Yachouh, Metn, Lebanon; Asaad Karam Building, Midan Street, Mazraat Yachouh, Lebanon; DOB 09 Jul 1955; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport RL2033216 (Lebanon) (individual) [SDGT].

37. KHANAFER, Hicham Nmer (a.k.a. KANAFER, Hicham; a.k.a. KANAFER, Hisham; a.k.a. KHANAFAR, Hisham; a.k.a. KHANAFIR, Hisham); DOB 23 May 1965; POB Ainata, Lebanon; alt. POB Kuntair, The Gambia; nationality Lebanon; alt. nationality The Gambia; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport 1617889 (Lebanon) (individual) [SDGT].

38. KUNTAR, Samir (a.k.a. AL-KUNTAR, Samir; a.k.a. CANTAR, Samir; a.k.a. KANTAR, Sameer; a.k.a. KINTAR, Samir; a.k.a. QANTAR, Samir; a.k.a. QINTAR, Samir; a.k.a. QUNTAR, Samir); DOB 20 Jul 1962; alt. DOB 1961; POB Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT] (Linked To: HIZBALLAH).

39. MANSUR, Muhammad Yusuf Ahmad (a.k.a. HALAWI, Hani; a.k.a. MANSOUR, Mohammad Yousef; a.k.a. MANSOUR, Mohammad Youssef; a.k.a. MANSUR, Mohammad Yusuf Ahmad; a.k.a. MANSUR, Muhammad Yusif Ahmad; a.k.a. SHEHAB, Sami; a.k.a. SHIHAB, Sami Hani; a.k.a. "HILLAWI, Jamal Hani"; a.k.a. "SAMI, Salem Bassem"; a.k.a. "SHIHAB, Muhammad Yusuf Mansur Sami"), Beirut, Lebanon; DOB 14 Sep 1970; alt. DOB 01 Jan 1974; alt. DOB 1980; POB Bint Jubayl, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

40. NASR AL DIN, Ghazi (a.k.a. NASR AL-DIN, Hajj Ghazi 'Atif; a.k.a. NASR EL DIN GHASSAN, Ghassan; a.k.a. NASRALDINE, Ghazi 'Atef; a.k.a. NASSER AL-DIN, Ghazil; a.k.a. NASSER EL-DIN, Gazi; a.k.a. NASSERDDINE, Ghassan Attef Salame; a.k.a. NASSERDDINE, Ghazi; a.k.a. NASSERDINE GHASAN, Atef Salameh; a.k.a. NASSEREDDINE, Ghazi; a.k.a. NASSEREDDINE, Haj Ghazzi; a.k.a. NASSEREDINE, Haj Ghazi; a.k.a. NASSERIDINE, Gazi); DOB 13 Dec 1962; POB Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

41. NASRALLAH, Hasan (a.k.a. NASRALLAH, Hasan Abd-al-Karim); DOB 31 Aug 1960; alt. DOB 31 Aug 1953; alt. DOB 31 Aug 1955; alt. DOB 31 Aug 1958; POB Al Basuriyah, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport 042833 (Lebanon); Secretary General of HIZBALLAH (individual) [SDT] [SYRIA].

42. NOUREDDINE, Mohamad (a.k.a. NUR-AL-DIN, Muhammad Mustafa); DOB 23 Oct 1974; POB Beirut, Lebanon; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Gender Male; Passport RL0629138 (Lebanon) (individual) [SDGT] (Linked To: HIZBALLAH).

43. OMAIRI, Farouk (a.k.a. AL-OMAIRI, Faruk; a.k.a. AL-UMAYRI, Faruz; a.k.a. OMAIRI, Farouk Abdul Haj; a.k.a. UMAIRI, Faruq), 605 Avenida Brasil, Apt No. 48, Foz do Iguacu, Brazil; DOB 06 Dec 1945; POB Hermel, Lebanon; citizen Brazil; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

44. QABALAN, Muhammad (a.k.a. QABLAN, Muhammad; a.k.a. "AL-GHUL, Hassan"), Southern Suburbs, Beirut, Lebanon; DOB 1969; citizen Lebanon;

Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

45. SALEH, Ali Mohamad (a.k.a. SALAH, Ali Mohammad; a.k.a. SALEH, Ali Mohamed; a.k.a. SALEH, Ali Mohammad; a.k.a. SALIH, Ali Abd-Al-Amir Muhammad; a.k.a. SALIH, Ali Muhammad; a.k.a. SALIH, Ali Muhammad Abd-Al-Amir); DOB 01 Jan 1974; POB Adchit, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Cedula No. 1124006380 (Colombia); Passport AJ911608 (Colombia); alt. Passport 2071362 (Lebanon); alt. Passport 1183967 (Lebanon) (individual) [SDNTK] [SDGT] (Linked To: ALMACEN BATUL; Linked To: COMERCIAL ESTILO Y MODA).

46. SERHAN, Fadi Hussein (a.k.a. SARHAN, Fadi Husayn; a.k.a. SIRHAN, Fadi), Own Building, Kanisat Marmkhael, Saliba Street, Corniche, Al-Mazraa, Beirut, Lebanon; Jaafar Building, Mazraa Street, Beirut, Lebanon; Jaafar Building, Mseytbi Street, Beirut, Lebanon; Jaafar Building, Salim Slam Street, Beirut, Lebanon; Jishi Building, Salim Slam Street, Beirut, Lebanon; Own Building, Main Street, Kfar Kila, Lebanon; DOB 01 Apr 1961; POB Kafr Kila, Lebanon; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Gender Male; Passport RL0962973 (Lebanon) (individual) [SDGT] (Linked To: HIZBALLAH).

47. SHALAN, Abd Al Nur (a.k.a. CHAALAN, Abdul Nur Ali; a.k.a. SHAALAN, Abdul Nur Ali; a.k.a. SHALAN, Abd Al Nur Ali; a.k.a. SHA'LAN, Abdul Nur Ali; a.k.a. SHALAN, Abdul-Nur Ali); DOB 17 May 1964; alt. DOB 1961; POB Baabda, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT] (Linked To: HIZBALLAH).

48. SHUKR, Fu'ad (a.k.a. CHAKAR, Fu'ad; a.k.a. "CHAKAR, Al-Hajj Mohsin"), Harat Hurayk, Lebanon; Ozai, Lebanon; Al-Firdaws Building, Al-'Arid Street, Haret Hreik, Lebanon; DOB 1962; POB An Nabi Shit, Ba'labakk, Biqa' Valley, Lebanon; alt. POB Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SYRIA] (Linked To: HIZBALLAH).

49. TABAJA, Adham Husayn (a.k.a. TABAJA, Adham Hussein; a.k.a. TABAJAH, Adham); DOB 24 Oct 1967; POB Kfartebnit 50, Lebanon; alt. POB Kfar Tibnit, Lebanon; alt. POB Ghobeiry, Lebanon; alt. POB Al Ghubayrah, Lebanon; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Gender Male; Passport RL1294089 (Lebanon); Identification Number 00986426 (Iraq) (individual) [SDGT] (Linked To: HIZBALLAH).

50. TAHINI, Abdallah Asad (a.k.a. THAHINI, Abdallah; a.k.a. THINI, Abdalla As'ad; a.k.a. "TAHINI, Ahmad"); DOB 20 Jun 1965; POB Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT] (Linked To: HIZBALLAH).

51. TAJIDEEN, Ali (a.k.a. TAGEDDINE, Ali Mohamed; a.k.a. TAJ AL DIN, Ali; a.k.a. TAJEDDIN, Ali Mohammad Abdel Hassan; a.k.a. TAJEDDIN, Ali Mohammad Abed Al-Hassan; a.k.a. TAJEDDINE, Ali); DOB 1961; alt. DOB 1963; POB Hanaway, Lebanon; alt. POB Hanouay, Lebanon; alt. POB Hanawiya, Lebanon; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

52. TAJIDEEN, Husayn (a.k.a. TAJ AL DIN, Husayn; a.k.a. TAJIDEEN, Hussein; a.k.a. TAJIDINE, Hajj Hussein), The Gambia; DOB 1963; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations (individual) [SDGT].

53. TARABAIN CHAMAS, Mohamad (a.k.a. CHAMS, Mohamad; a.k.a. TARABAY, Muhammad; a.k.a. TARABAYN SHAMAS, Muhammad), Avenida Jose Maria De Brito 606, Apartment 51, Foz do Iguacu, Brazil; Cecilia Meirelles 849, Bloco B, Apartment 09, Foz do Iguacu, Brazil; DOB 11 Jan 1967; POB Asuncion, Paraguay; alt. citizen Lebanon; alt. citizen Brazil; alt. citizen Paraguay; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; National Foreign ID Number RNE: W031645–8 (Brazil) (individual) [SDGT].

54. WEHBE, Bilal Mohsen (a.k.a. WAHBE, Bilal; a.k.a. WAHBI, Bilal Mohsen; a.k.a. WAHBI, Bilal Muhsin; a.k.a. WAHBI, Muhsin Bilal; a.k.a. WEHBI, Bilal Mohsem; a.k.a. WEHBI, Bilal Mohsen; a.k.a. WIHBI, Bilal Muhsin), Avenida Jose Maria de Brito 929, Centro,, Foz Do Iguacu, Parana State, Brazil; DOB 07 Jan 1967; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport CZ74340 (Brazil); alt. Passport 0083628 (Lebanon); Identification Number 77688048 (Brazil); Shaykh (individual) [SDGT].

55. ZAHER EL DINE, Hamdi (a.k.a. ZAHREDDINE, Hamdi); DOB 20 Jul 1984; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Gender Male; Passport RL2146270 (Lebanon) (individual) [SDGT] (Linked To: HIZBALLAH).

56. ZEAITER, Ali (a.k.a. ZOEITER, Ali; a.k.a. ZU'AYTAR, 'Ali; a.k.a. ZU'AYTIR, Ali Husayn), Tianhelu 351 Hao, Tianhequ, Guangzhou, China; Room 2203A, Grand Tower, No. 228 Tianhe Road, Tianhe District, Guangzhou, China; Room 2203A, Guangcheng Building, No. 228 Tianhe Road, Guangzhou, China; 204 No. 253 Tianhebei Road, Guangzhou, China; DOB 24 Feb 1977; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport RL1924321 (Lebanon); alt. Passport RL0877465 (Lebanon); General Manager, Stars International Ltd (individual) [SDGT].

57. ZURAIK, Ali Hasan (a.k.a. ZRAIQ, Ali; a.k.a. ZREIK, Ali; a.k.a. ZREIK, Ali Hassan; a.k.a. ZURAYQ, Ali); DOB 1952; POB Al Khiyam, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Passport RL0266714 (Lebanon); alt. Passport 1082625 (Lebanon) (individual) [SDGT].

Entities

1. AERO SKYONE CO. LIMITED (a.k.a. AERO SKY ONE LTD; a.k.a. AEROSKYONE CO. LTD), Tianhe Qu, Tianhe Bei Lu, 255 Hao, 1606 Fang, Guangzhou, China; Room 1501 (340), 15/F, SPA Center, 53–55 Lockhart Road, Wan Chai, Hong Kong; Room 1501 (340), Lockhart, Wan Chai, Hong Kong; Web site *www.aerskyone.com;* Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: ZEAITER, Ali).

2. AL MANAR TV, Al Manar TV, Abed al Nour Street, Haret Hriek, Beirut, Lebanon; PO Box 354/25, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; *info@manartv.com; www.manartv.com; www.almanar.com.lb* [SDGT].

3. AL NOUR RADIO (a.k.a. AL NOUR BROADCASTING STATION; a.k.a. AL NUR RADIO; a.k.a. RADIO ANNOUR), Abed Al Nour Street, PO Box 197/25, Alghobeiri, Haret Hriek, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; *info@al-nour.net; www.al-nour.net* [SDGT].

4. AL-INMAA ENGINEERING AND CONTRACTING (a.k.a. AL-INMAA GROUP FOR ENGINEERING AND CONTRACTING; a.k.a. INMAA 'AL' FOR ENGINEERING AND CONTRACTING SARL), Ground Floor, Inmaa Building, New Airport Highway, Beirut, Lebanon; Airport Highway, Bir Hassan, Beirut, Lebanon; Aljadriya, Baghdad, Iraq; Aljazzar Road, Basra, Iraq; Al-Jaza'ir Street, 'Oman Neighborhood, Basra, Iraq; Web site *www.alinmaa.com.lb;* Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: TABAJA, Adham Husayn; Linked To: AL-INMAA GROUP FOR TOURISM WORKS, LLC).

5. AL-INMAA FOR ENTERTAINMENT AND LEISURE PROJECTS (a.k.a. AL-INMAA FOR ENTERTAINMENTS AND LEISURE PROJECTS; a.k.a. AL-INMAA GROUP FOR ENTERTAINMENT AND LEISURE PROJECTS), Ground Floor, Al Rabieh Building, New Airport Highway, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: AL-INMAA GROUP FOR TOURISM WORKS, LLC).

6. AL-INMAA GROUP FOR TOURISM WORKS, LLC (a.k.a. AL-INMAA GROUP; a.k.a. AL-INMAA GROUP FOR TOURISM WORK, LLC; a.k.a. AL-INMAA GROUP, LLC), Al-Inmaa Group Building, New Airport Highway, Beirut, Lebanon; Web site *www.alinmaa-group.com;* Additional

Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Commercial Registry Number 8–0788 (Lebanon) [SDGT] (Linked To: TABAJA, Adham Husayn).

7. AL-QARD AL-HASSAN ASSOCIATION (a.k.a. AL-QUARD AL-HASSAN ASSOCIATION; a.k.a. AL-QUARDH AL-HASSAN ASSOCIATION; a.k.a. KARADH AL-HASSAN), Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT].

8. AMIGO SUPERMARKET LIMITED (a.k.a. AMIGO SUPERMARKET), 1023, Adetokunbo Ademola Crescent, Wuse II, Abuja, Nigeria; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: FAWAZ, Mustapha Reda Darwish; Linked To: FAWAZ, Fouzi Reda Darwish).

9. BARAKAT IMPORT EXPORT LTDA, Iquique, Chile; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Tax ID No. AABA 670850 Y [SDGT].

10. BAYT AL-MAL (a.k.a. BAYT AL-MAL LIL MUSLIMEEN), Harat Hurayk, Beirut, Lebanon; Burj al-Barajinah, Lebanon; Sidon, Lebanon; Tyre, Lebanon; Al-Nabatiyah, Lebanon; Ba'albak, Lebanon; Hirmil, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT].

11. BIBLOS TRAVEL AGENCY (a.k.a. BIBLIOS TRAVEL; a.k.a. BIBLOS TRAVEL CA; a.k.a. BIBLOS TRAVEL, C.A.), Avenida Baralt, Esquina Maderero, Edificio Santa Isabel II, PB, Loc. 1, Caracas, Venezuela; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT].

12. CAR CARE CENTER (a.k.a. CAR CARE CENTER CCC; a.k.a. CAR CARE CENTER COMPANY; a.k.a. "CCC COMPANY"), Hadeth Kafaat, Hadi Nasrallah Highway, Baabda, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: HIZBALLAH).

13. CASA APOLLO, Galeria Page, Ciudad del Este, Paraguay; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT].

14. FASTLINK SARL (a.k.a. FAST LINK SAL), Hadi Nasrallah Av, MEAB Building, 1st Floor, Beirut, Lebanon; Cendrella Street, Dalas Center, Chyah, Baabda, Lebanon; Dallas, 6th Floor, Saida Old Road, Chiyah, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: STARS GROUP HOLDING).

15. GALERIA PAGE (a.k.a. GALERIA PAGE I), 899 Calle Regimento Pirebebuy, Ciudad del Este, Paraguay; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT].

16. GOODWILL CHARITABLE ORGANIZATION, INC. (f.k.a. AL-SHAHID SOCIAL ASSOCIATION; f.k.a. EDUCATIONAL DEVELOPMENT ASSOCIATION), 13106 Warren Ave. Suite #4, Dearborn, MI 48126, United States; PO Box 1794, Dearborn, MI 48126, United States; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT].

17. HILAL TRAVEL AGENCY (a.k.a. HILAL TRAVEL C.A.; a.k.a. KANAAN TRAVEL), Avenida Baralt, Esquina Maderero, Edificio Santa Isabel, Caracas, Venezuela; Avenida Baralt, Esquina Maderero, Edificio Santa Isabel, PB, Local 1, Caracas, Venezuela; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Business Registration Document # 80074366 (Venezuela) [SDGT].

18. HIZBALLAH (a.k.a. ANSAR ALLAH; a.k.a. FOLLOWERS OF THE PROPHET MUHAMMED; a.k.a. ISLAMIC JIHAD; a.k.a. ISLAMIC JIHAD FOR THE LIBERATION OF PALESTINE; a.k.a. ISLAMIC JIHAD ORGANIZATION; a.k.a. ORGANIZATION OF RIGHT AGAINST WRONG; a.k.a. ORGANIZATION OF THE OPPRESSED ON EARTH; a.k.a. PARTY OF GOD; a.k.a. REVOLUTIONARY JUSTICE ORGANIZATION); Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [FTO] [SDGT] [SDT] [SYRIA].

19. IMAM KHOMEINI RELIEF COMMITTEE (LEBANON BRANCH) (a.k.a. COMITE ISLAMIQUE DAIDES ET DE BIEM LIBAN; a.k.a. EMDAD ASSISTANCE FOUNDATION; a.k.a. EMDAD COMMITTEE FOR ISLAMIC CHARITY; a.k.a. IMAM KHOMEINI EMDAD COMMITTEE; a.k.a. IMAM KHOMEINI FOUNDATION; a.k.a. IMAM KHOMEINI IMDAD COMMITTEE; a.k.a. IMAM KHOMEINI RELIEF ORGANIZATION; a.k.a. IMAM KHOMEINI SUPPORT COMMITTEE; a.k.a. IMAM KHOMEINY AID COMMITTEE; a.k.a. IMDAD ASSOCIATION OF THE ISLAMIC PHILANTHROPIC COMMITTEE; a.k.a. IMDAD COMMITTEE FOR ISLAMIC CHARITY; a.k.a. IMDAD ISLAMIC ASSOCIATION COMMITTEE FOR CHARITY; a.k.a. ISLAMIC CHARITY EMDAD; a.k.a. ISLAMIC CHARITY EMDAD COMMITTEE; a.k.a. ISLAMIC EMDAD CHARITABLE COMMITTEE; a.k.a. KHOMEINI CHARITABLE FOUNDATION; a.k.a. KHOMEINI SOCIAL HELP COMMITTEE; a.k.a. KOMITE EMDAD EMAM; a.k.a. "AL-IMDAD"), P.O. Box 25–211 Beirut AiRabi' Building, 2nd Floor,, Mokdad Street, Haret Hreik, Beirut, Lebanon; P.O. Box 25/221 El Ghobeiry, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions; alt. Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] [IFSR].

20. ISLAMIC RESISTANCE SUPPORT ORGANIZATION (a.k.a. HAYAT AL-DAM LIL-MUQAWAMA AL-ISLAMIYA; a.k.a. ISLAMIC RESISTANCE SUPPORT ASSOCIATION), Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT].

21. JIHAD AL-BINA (a.k.a. CONSTRUCTION FOR THE SAKE OF THE HOLY STRUGGLE; a.k.a. CONSTRUCTION JIHAD; a.k.a. HOLY CONSTRUCTION FOUNDATION; a.k.a. JIHAD AL BINAA; a.k.a. JIHAD CONSTRUCTION; a.k.a. JIHAD CONSTRUCTION FOUNDATION; a.k.a. JIHAD CONSTRUCTION INSTITUTION; a.k.a. JIHAD-AL-BINAA ASSOCIATION; a.k.a. JIHADU-I-BINAA; a.k.a. STRUGGLE FOR RECONSTRUCTION), Beirut, Lebanon; Bekaa Valley, Lebanon; Southern Lebanon, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT].

22. KAFAK ENTERPRISES LIMITED, 88B, T/Balewa Road, Kano State, Nigeria; Sierra Leone; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: FAWAZ, Mustapha Reda Darwish; Linked To: FAWAZ, Fouzi Reda Darwish).

23. KAIRABA SUPERMARKET (a.k.a. KAIRABA SHOPPING CENTER), Kairaba Ave, P.O. Box 2176, Banjul, The Gambia; 62 Buckle Street, Banjul, The Gambia; Pipeline Road, Banjul, The Gambia; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT].

24. LABICO SAL OFFSHORE (a.k.a. LABICO SAL (OFF SHORE)), Bou Ghannam Building, Azhar Street, Kobbe Doha, Aramoun, Aaley, Lebanon; Labico Building, Azhar Street, Aramoun, Aaley, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: ZEAITER, Ali).

25. LEBANESE MEDIA GROUP (a.k.a. LEBANESE COMMUNICATION GROUP), Al Manar Building, Ahmad Kassir Street, Haret Hriek, Baabda, Lebanon; Abed Al Nour Street, Haret Hriek, PO Box 354/25, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Company ID: No. 59 531 at Commercial Registry of the Civil Court of First Instance at Baabda, Lebanon [SDGT].

26. LE-HUA ELECTRONIC FIELD CO. LIMITED (a.k.a. LE-HUA ELEC F CO. LTD), Room B, 5/F, Building 2, Guilong Jiayuan Gui Yuan North Road, Guiyuan Neighborhood St Office, Luohu District, Shenzhen, Guangdong, China; 15th Floor, Ming Shang Ge Building, Bao'an Street, Luo Hu Area, Shenzhen, Guangdong, China; Flat/Room 1610, Nan Fung Tower, 173 Des Voeux Road Central, Hong Kong; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: CHERRI, Adel Mohamad).

27. MARTYRS FOUNDATION (a.k.a. AL-SHAHID ASSOCIATION FOR MARTYRS AND INTERNEES FAMILIES; a.k.a. AL-SHAHID CORPORATION; a.k.a. BONYAD SHAHID; a.k.a. BONYAD-E SHAHID; a.k.a. BONYAD-E SHAHID VA ISARGARAN; a.k.a.

ES-SHAHID; a.k.a. IRANIAN MARTYRS FUND; a.k.a. SHAHID FOUNDATION; a.k.a. SHAHID FOUNDATION OF THE ISLAMIC REVOLUTION), P.O. Box 15815–1394, Tehran 15900, Iran; Additional Sanctions Information—Subject to Secondary Sanctions; alt. Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] [IFSR].

28. MARTYRS FOUNDATION IN LEBANON (a.k.a. AL-MUA'ASSAT AL-SHAHID; a.k.a. AL-SHAHID CHARITABLE AND SOCIAL ORGANIZATION; a.k.a. AL-SHAHID FOUNDATION; a.k.a. AL-SHAHID ORGANIZATION; a.k.a. HIZBALLAH MARTYRS FOUNDATION; a.k.a. ISLAMIC REVOLUTION MARTYRS FOUNDATION; a.k.a. LEBANESE MARTYR ASSOCIATION; a.k.a. LEBANESE MARTYR FOUNDATION; a.k.a. MARTYRS INSTITUTE), P.O. Box 110 24, Bir al-Abed, Beirut, Lebanon; Biqa' Valley, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT].

29. PALESTINIAN MARTYRS FOUNDATION (a.k.a. AL-SHAHID FOUNDATION- PALESTINIAN BRANCH; a.k.a. MUASSASAT SHAHID FILISTIN; a.k.a. PALESTINIAN MARTYRS INSTITUTION GROUP; a.k.a. SHAHID FUND), Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT].

30. SPECTRUM INVESTMENT GROUP HOLDING SAL (a.k.a. SPECTRUM INTERNATIONAL INVESTMENT HOLDING SAL; a.k.a. SPECTRUM INVESTMENT GROUP HOLDING; a.k.a. SPECTRUM INVESTMENT GROUP SAL HOLDING; a.k.a. SPECTRUM INVESTMENT HOLDING; a.k.a. "SPECTRUM HOLDING"), Floor 17, Verdun 732 Building, Rachid Karameh Street, Verdun, Beirut, Lebanon; Verdun 732 Center, Rachid Karame Street, Beirut, Lebanon; P.O. Box 113–5333, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Business Registration Document # 1990106 (Lebanon) [SDGT] (Linked To: CHARARA, Ali Youssef).

31. STARS COMMUNICATIONS LTD (a.k.a. STARS COMMUNICATIONS; a.k.a. STARS COMMUNICATIONS LLC; a.k.a. STARS COMMUNICATIONS LTD SARL), Hadi Nasrallah Av, MEAB Building, 1st Floor, Beirut, Lebanon; Bir el Abed, Snoubra Street, Haret Hreyk, Beirut, Lebanon; Tayyouneh, Haret Hreyk, Beirut, Lebanon; Port, Nahr, Beirut, Lebanon; Ras El Ain, Baalbeck, Lebanon; Hadeth, Lebanon; Nabatiyeh, Lebanon; Old Saida Road, Beirut Mall, Beirut, Lebanon; Duty-Free Airport, Rafik Hariri International Airport, Beirut, Lebanon; Sharl Helo Street, Beirut Seaport, Lebanon; Kamil Shamoun Street, Dekwaneh, Beirut, Lebanon; Hermel, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Commercial Registry Number 2001929 (Lebanon) [SDGT] (Linked To: AMHAZ, Kamel Mohamad; Linked To: STARS GROUP HOLDING).

32. STARS COMMUNICATIONS OFFSHORE SAL (a.k.a. STARS COMMUNICATION SAL OFF-SHORE; a.k.a. STARS COMMUNICATIONS OFFSHORE; a.k.a. STARS OFFSHORE), Hojeij Building, 2nd Floor, Zaghloul Street, Haret Hreik, Baabda, Lebanon; Bdeir Building, Ground Floor, Snoubra Street, Ghobeiry, Baabda, Lebanon; Hadi Nasrallah Av, MEAB Building, 1st Floor, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Commercial Registry Number 1801374 (Lebanon) [SDGT] (Linked To: STARS GROUP HOLDING).

33. STARS GROUP HOLDING (a.k.a. STARS GROUP HOLDING SAL; a.k.a. STARS GROUP SAL (HOLDING)), Property Number 5208/62, Issam Mohamed Amha, 6th Floor, Dallas Center, Old Saida Road, C, Lebanon; Postal Box 13–5483, Lebanon; Bdeir Building, Snoubra Street, Bir El-Abed Area, Haret Hreik, Baabda, Lebanon; Bir El Abed, Hadi Nasrallah Highway, Middle East & Africa Bank Building, First Floor, Beirut, Lebanon; Old Saida Road, Dallas Center, 6th Floor, Beirut, Lebanon; Web site *www.starscom.net;* Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Commercial Registry Number 1901453 (Lebanon) [SDGT] (Linked To: AMHAZ, Kamel Mohamad).

34. STARS INTERNATIONAL LTD (a.k.a. STARS INTERNATIONAL CO. LTD), Room 2203A, Grand Tower, No. 228 TianHe Road, TianHe District, Guangzhou, China; F–18, Dubai Airport Free Zone, Dubai, United Arab Emirates; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: ZEAITER, Ali; Linked To: STARS GROUP HOLDING).

35. TAJCO (a.k.a. GRAND STORES (THE GAMBIA LOCATION ONLY); a.k.a. TAJCO COMPANY; a.k.a. TAJCO COMPANY LLC; a.k.a. TAJCO LTD; a.k.a. TAJCO SARL; a.k.a. TRADEX CO), 62 Buckle Street, Banjul, The Gambia; 1 Picton Street, Banjul, The Gambia; Dohat Building 1st Floor, Liberation Avenue, Banjul, The Gambia; Tajco Building, Main Street, Hannawiyah, Tyre, Lebanon; Tajco Building, Hanouay, Sour (Tyre), Lebanon; 30 Sani Abacha Street, Freetown, Sierra Leone; Web site *www.tajco-ltd.com;* Web site *www.tajcogambia.com;* Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; (Tradex Co. is a subsidiary of Tajco Company and operates from the same business address in Freetown, Sierra Leone as Tajco Company.) [SDGT].

36. TELESERVE PLUS SAL (a.k.a. TELESERVEPLUS), 4th Floor, Dalas Center, Old Saida Road, Chiyah, Baabda, Lebanon; Postal Box 13–5483, Lebanon; Old Saida Avenue, Dallas Center, 6th Floor, Beirut, Lebanon; 6th Floor, Dallas Center, Old Saida Road, Chiyah, Baabda, Lebanon; Web site *www.teleserveplus.com;* Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Commercial Registry Number 2004609 (Lebanon) [SDGT] (Linked To: STARS GROUP HOLDING).

37. TRADE POINT INTERNATIONAL S.A.R.L., 3rd Floor, Gulf Building, Block B, Hafez Al Asad Street, Airport Highway, Bir Hassan, Beirut, Lebanon; Gulf Building, 3rd Floor, Hafiz Al Asad Autostrade, Ghobeiri, Baabda, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Registration ID 2020615 [SDGT] (Linked To: NOUREDDINE, Mohamad).

38. UNIQUE STARS MOBILE PHONES LLC (a.k.a. UNIQUE STARS LLC), Postal Box 98498, Dubai, United Arab Emirates; Al Maktoum Road, Deira, Al Kabira Building, First Floor, Office #103, PO Box 98498, Dubai, United Arab Emirates; Office 103, 1st Floor, Sheikh Rashed Building, Al Maktoum Road, Deira, DXB Municipality, Dubai, United Arab Emirates; Gargash Center, Nasser Square, Shop No. 41, Dubai, United Arab Emirates; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Dubai Chamber of Commerce Membership No. 116340; Commercial Registry Number 591610 (United Arab Emirates) [SDGT] (Linked To: IBRAHIM, Ayman; Linked To: STARS GROUP HOLDING).

39. VATECH SARL (a.k.a. VATECH LEBANON; a.k.a. VATECH VIDEO AND PRO AUDIO; a.k.a. "VATECH"), P.O. Box 14–5728, Jishi Building, Salim Slam Street, Mazraa, Beirut, Lebanon; P.O. Box 14–5728, Borj al Salam Building, Salim Slam Street, Beirut, Lebanon; Jaafar Building, Mazraa Street, Beirut, Lebanon; Jaafar Building, Moseitbi Street, Beirut, Lebanon; Jaafar Building, Salim Slam Street, Mazraa, Beirut, Lebanon; Jishi Building, Mazraa Street, Beirut, Lebanon; Web site *www.vatech.com.lb;* Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: SERHAN, Fadi Hussein).

40. WAAD PROJECT (a.k.a. AL-WAAD AL-SADIQ; a.k.a. 'MASHURA WAAD LAADAT AL-AAMAR; a.k.a. WAAD; a.k.a. WA'AD AS SADIQ; a.k.a. WAAD COMPANY; a.k.a. WAAD FOR REBUILDING THE SOUTHERN SUBURB; a.k.a. WAAD PROJECT FOR RECONSTRUCTION; a.k.a. WA'D PROJECT; a.k.a. WAED; a.k.a. WA'ED ORGANIZATION; a.k.a. WA'ID COMPANY), Harat Hurayk, Lebanon; Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Telephone No. 009613679153; Telephone No. 009613380223; Telephone No. 03889402; Telephone No. 03669916 [SDGT].

41. WONDERLAND AMUSEMENT PARK AND RESORT LTD (a.k.a. WONDERLAND AMUSEMENT PARK), B1 Kukbawa, Opposite National Stadium, Abuja, FCT, Nigeria; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: FAWAZ, Mustapha Reda Darwish; Linked To: FAWAZ, Fouzi Reda Darwish).

42. YOUSSER COMPANY FOR FINANCE AND INVESTMENT, Lebanon; Additional Sanctions Information—Subject to Secondary

Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT].

Dated: May 13, 2016.

John E. Smith,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2016–11684 Filed 5–17–16; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 4506T–EZ, 4506–T–EZ (SP)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 4506T–EZ, Short Form Request for Individual Tax Return Transcript, and 4506T–EZ(SP), Formulario Abreviado para la Solicitud de un Trasunto de la Declaracion de Impuestos Personales.

DATES: Written comments should be received on or before July 18, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to R. Joseph Durbala, (202) 317–5746, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Short Form Request for Individual Tax Return Transcript (4506T–EZ); Formulario Abreviado para la Solicitud de un Trasunto de la Declaracion de Impuestos Personales (4506T–EZ(SP)).

OMB Number: 1545–2154.

Form Number: Form 4506T–EZ, Form 4506T–EZ (SP).

Abstract: Subject to such requirements and conditions as the Secretary may prescribe by regulation, section 6103(c) of the Internal Revenue Code authorizes the Internal Revenue Service to disclose a taxpayer's return or return information to such person or persons as the taxpayer may designate in a request for or consent to such disclosure, or to any other person at the taxpayer's request to the extent necessary to comply with the taxpayer's request to such other person for information or assistance. This regulation (§ 301.6103(c)–1), contains the requirements that must be met before, and the conditions under which, the Internal Revenue Service may make such disclosures.

Individuals can use Form 4506T–EZ to request a tax return transcript that includes most lines of the original tax return. The tax return transcript will not show payments, penalty assessments, or adjustments made to the originally filed return. Form 4506T–EZ (SP) is the Spanish translated version of the Form 4507T–EZ. It is also used to request a tax return transcript that includes most lines of the original tax return.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or Households, Farms, and Businesses and other for-profit organizations.

Estimated Number of Respondents: 1,100,000.

Estimated Time per Respondent: 47 minutes.

Estimated Total Annual Burden Hours: 870,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 9, 2016.

R. Joseph Durbala,

IRS Tax Analyst.

[FR Doc. 2016–11650 Filed 5–17–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments on the information collection burden relating to basis and transfer statement reporting for covered securities, including debt instruments, options, and other securities.

DATES: Written comments should be received on or before July 18, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Sara Covington, at Internal Revenue Service, room 6526, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet, at *Sara.L.Covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: T.D. 9504—Basis Reporting by Securities Brokers and Basis Determination for Stock;

T.D. 9616—Basis Reporting by Securities Brokers and Basis

Determination for Debt Instruments and Options;

T.D. 9713—Basis Reporting by Securities Brokers and Basis Determination for Debt Instruments and Options;

T.D. 9750—Basis and Transfer Reporting by Securities Brokers for Debt Instruments and Options.

OMB Number: 1545–2186.

Regulation Project Number: REG–101896–09, REG–102988–11, REG–154563–12, and REG–143040–14.

Abstract: The final regulations under section 6045 provide rules on basis reporting by brokers for transactions involving covered securities, including debt instruments and options. The final regulations under section 6045A provide reporting rules that apply upon a transfer of a covered security from one broker to another broker. These final regulations under sections 6045 and 6045A reflect changes in the law made by the Energy Improvement and Extension Act of 2008, Division B of Public Law 110–343 (122 Stat. 3765, 3854 (2008)), that require brokers when reporting the sale of a covered security to the IRS to include the customer's adjusted basis in the sold securities and to classify any gain or loss as long-term or short-term. The information collected for covered securities under § 1.6045–1, including § 1.6045–1(c)(3)(xi)(C) (relating to short sales), and § 1.6045A–1 allows a broker who effects a sale of a transferred covered security, including a debt instrument or option, to determine and report the adjusted basis of the security and whether any gain or loss with respect to the sale is ordinary (for certain debt instruments), long-term, or short-term in compliance with section 6045(g) of the Internal Revenue Code. The information collected under § 1.6045–1(n)(5) relates to information required to be reported by the holder of a debt instrument to a broker for certain holder elections that affect how the debt instrument's basis is computed, which will enable the broker to comply with its reporting obligations under section 6045(g).

Current Actions: There are changes to these existing regulations.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses or other for-profit institutions and individuals or households.

Estimated Number of Respondents: 79,000.

Estimated Total Annual Responses: 11,211,500.

Estimated Total Burden Hours: 694,750.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 3, 2016.

Tuawana Pinkston,

IRS Supervisory Tax Analyst.

[FR Doc. 2016–11656 Filed 5–17–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning source of income from certain space and ocean activities; source of communications income.

DATES: Written comments should be received on or before July 18, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, room 6528, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to R. Joseph Durbala at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 317–5746, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Source of Income from Certain Space and Ocean Activities; Source of Communications Income.

OMB Number: 1545–1718.

Regulation Project Number: TD 9305.

Abstract: TD 9305 contains final regulations under section 863(d) governing the source of income from certain space and ocean activities. The final regulations primarily affect persons who derive income from activities conducted in space, or on or under water not within the jurisdiction of a foreign country, possession of the United States, or the United States (in international water). The final regulations also affect persons who derive income from transmission of communications.

Current Actions: There is no change to these existing regulations.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents/Recordkeepers: 250.

Estimated Average Time Per Respondent/Recordkeeper: 5 hours.

Estimated Total Annual Reporting/Recordkeeping Hours: 1,250.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 11, 2016.

R. Joseph Durbala,

IRS Tax Analyst.

[FR Doc. 2016–11649 Filed 5–17–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8404

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8404, Interest Charge on DISC-Related Deferred Tax Liability.

DATES: Written comments should be received on or before July 18, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6528, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to R. Joseph Durbala, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Interest Charge on DISC-Related Deferred Tax Liability.

OMB Number: 1545–0939.

Form Number: 8404.

Abstract: Shareholders of Interest Charge Domestic International Sales Corporations (IC–DISCs) use Form 8404 to figure and report an interest charge on their DISC-related deferred tax liability. The interest charge is required by Internal Revenue Code section 995(f). IRS uses Form 8404 to determine whether the shareholder has correctly figured and paid the interest charge on a timely basis.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations and individuals.

Estimated Number of Responses: 2,000.

Estimated Time per Response: 7 hrs., 47 min.

Estimated Total Annual Burden Hours: 15,580.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 10, 2016.

R. Joseph Durbala,

Tax Analyst, IRS.

[FR Doc. 2016–11665 Filed 5–17–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 2439

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 2439, Notice to Shareholder of Undistributed Long-Term Capital Gains.

DATES: Written comments should be received on or before July 18, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to R. Joseph Durbala, at (202) 317–5746, or at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet, at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Notice to Shareholder of Undistributed Long-Term Capital Gains.

OMB Number: 1545–0145.

Form Number: 2439.

Abstract: Form 2439 is used by regulated investment companies or real estate investment trusts to show shareholders the amount of tax paid on undistributed capital gains under section 852(b)(3)(D) or 857(b)(3)(D).

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 6,275.

Estimated Time per Respondent: 4 hrs., 47 min.

Estimated Total Annual Burden Hours: 29,995.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 9, 2016.

R. Joseph Durbala,

IRS Tax Analyst.

[FR Doc. 2016–11655 Filed 5–17–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8816

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8816, Special Loss Discount Account and Special Estimated Tax Payments for Insurance Companies.

DATES: Written comments should be received on or before July 18, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to R. Joseph Durbala, at (202) 317–5746, or at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet, at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Special Loss Discount Account and Special Estimated Tax Payments for Insurance Companies.

OMB Number: 1545–1130

Form Number: 8816.

Abstract: Form 8816 is used by insurance companies claiming an additional deduction under Internal Revenue Code section 847 to reconcile estimated tax payments and to determine their tax benefit associated with the deduction. The information is needed by the IRS to determine that the proper additional deduction was claimed and to insure the proper amount of special estimated tax was computed and deposited.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 3,000.

Estimated Time Per Respondent: 6 hrs., 37 min.

Estimated Total Annual Burden Hours: 19,830.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 9, 2016.

R. Joseph Durbala,

IRS Tax Analyst.

[FR Doc. 2016–11648 Filed 5–17–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8498

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8498, Continuing Education Provider Application and Request for Provider Number.

DATES: Written comments should be received on or before July 18, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to

R. Joseph Durbala at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 317–5746, or through the internet, at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Continuing Education Provider Application and Request for Provider Number.

OMB Number: 1545–1459.

Form Number: Form 8498.

Abstract: Form 8498 is used by the Director of Practice to determine the qualifications of those individuals or organizations seeking to present continuing professional educational programs for persons enrolled to practice before the Internal Revenue Service.

Current Actions: There is no change in the form previously approved by OMB. However, we are increasing the estimated number of annual responses to account for an estimated increase in submissions. This will result in an annual burden increase of 180 hours per year.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals and business or other for-profit organizations.

Estimated Number of Respondents: 800.

Estimated Time per Respondent: 36 minutes.

Estimated Total Annual Burden Hours: 480.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 9, 2016.

R. Joseph Durbala,

Tax Analyst, IRS.

[FR Doc. 2016–11654 Filed 5–17–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Advisory Committee on Rehabilitation; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that a meeting of the Veterans' Advisory Committee on Rehabilitation (VACOR) will be held on Wednesday, June 15, 2016, via teleconference, from 1:00 p.m. (EST) until 3:00 p.m. (EST). The meeting is open to the public.

The purpose of the Committee is to provide advice to the Secretary on the rehabilitation needs of Veterans with disabilities and on the administration of VA's rehabilitation programs.

During the meeting, Committee members will participate in new members' orientation and review administrative guidelines. The primary agenda topics will be to discuss the purpose, vision and direction of VACOR.

Although no time will be allocated for receiving oral presentations from the public, members of the public may submit written statements for review by the Committee to Anthony Estelle, Designated Federal Officer, Veterans Benefits Administration (28), 810 Vermont Avenue NW., Washington, DC 20420, or via email at *Anthony.Estelle@va.gov.* In the communication, writers must identify themselves and state the organization, association or person(s) they represent.

Individuals who wish to call in to the meeting should RSVP to Anthony Estelle at (202) 461–9912, no later than close of business, June 8, 2016. The dial in number to attend the conference is: 1–800–767–1750. At the prompt, enter access code 33489 then press #. During the day of the meeting, please call in at least 15 minutes prior to the start of the meeting; callers will not be given access after 1:00 p.m. Any member of the public seeking additional information should contact Anthony Estelle at the phone number or email address noted above.

Dated: May 13, 2016.

Jelessa Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2016–11680 Filed 5–17–16; 8:45 am]

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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Wednesday,
No. 96 May 18, 2016

Part II

Department of Justice

Drug Enforcement Administration

Superior Pharmacy I and Superior Pharmacy II; Decision and Order; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket Nos. 15–6 and 15–7]

Superior Pharmacy I and Superior Pharmacy II Decision and Order

This is a consolidated proceeding involving two pharmacies located in Tampa, Florida with common ownership. On October 8, 2014, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration issued an Order to Show Cause to Superior Pharmacy, L.L.C. (hereinafter, Superior II), which proposed the revocation of its DEA Certificate of Registration BS9699731, pursuant to which it is authorized to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered location of 5416 Town 'N' Country Blvd. ALJ Ex. 1, at 1 (No. 15–7). The next day, the Deputy Assistant Administrator issued an Order to Show Cause to Superior Pharmacy, L.L.C. (hereinafter, Superior I), which proposed the revocation of its DEA Certificate of Registration BS9255274, pursuant to which it is authorized to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered location of 3007 W. Cypress Street, Suite 1. ALJ Ex. 1, at 1 (No. 15–6).

As grounds for the proposed actions (which also included the denial of any pending applications), the Show Cause Orders alleged that each pharmacy's "continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f)." *Id.; see also* ALJ Ex. 1, at 1 (No. 15–7); 21 U.S.C. 824(a)(4). Specifically, with respect to each pharmacy, the Orders alleged that their "pharmacists repeatedly failed to exercise their corresponding responsibility to ensure that controlled substances they dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice" and that their "pharmacists ignored readily identifiable red flags that [the] controlled substances prescribed were being diverted and dispensed despite unresolved red flags." ALJ Ex. 1, at 1 (No. 15–6); ALJ Ex. 1, at 1 (No. 15–7) (both citing 21 CFR 1306.04(a); *Holiday CVS. L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195,* 77 FR 62315, 62319 (2012)).

The Show Cause Orders further alleged that each pharmacy's "pharmacists dispensed controlled substances when they knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacist knew or should have known that the controlled substances were abused and/or diverted by the customer." ALJ Ex. 1, at 2 (No. 15–6); ALJ Ex. 1, at 2 (No. 15–7). Each Show Cause Order then listed various red flags which each Respondent's pharmacists allegedly failed to resolve before dispensing prescriptions, including: (1) "Multiple individuals presenting prescriptions for the same drugs in the same quantities from the same doctor"; (2) "individuals presenting prescriptions for controlled substances known to be highly abused, such as oxycodone and hydromorphone"; (3) "individuals paying . . . for controlled substances with cash";[1] and (4) "individuals residing long distances from the pharmacy." ALJ Ex. 1, at 2 (No. 15–6); ALJ Ex. 1, at 2 (No. 15–7). Each Show Cause Order then set forth allegations of specific instances in which Respondents' pharmacists dispensed oxycodone 30 mg or hydromorphone 8 mg without resolving various red flags presented by the patients and/or the prescriptions; the Order further alleged that several of these prescriptions were facially invalid because they lacked the patient's address. ALJ Ex 1, at 2 (No. 15–6); ALJ Ex. 1, at 2 (No. 15–7).

Each Show Cause Order further alleged that Respondents' pharmacists dispensed hydromorphone, notwithstanding that the "dosage amounts . . . if taken as directed, far exceeded the recommended dosages of hydromorphone that should be taken on a daily basis." ALJ Ex. 1, at 2 (No. 15–6); ALJ Ex. 1, at 3 (No. 15–7). The Superior I Order also alleged that its pharmacists dispensed prescriptions, which were written by the same doctor on the same day, for "large and substantially similar quantities of" oxycodone 30 mg, "to two customers . . . both of whom resided at the same address," in a town "located approximately [449 miles] from" the pharmacy. ALJ Ex. 1, at 2 (No. 15–6). Likewise, the Superior II order alleged that its "pharmacists dispensed large and substantially similar quantities of hydromorphone and oxycodone to two individuals with the same last name who received their prescriptions on the same day from doctors at the same clinic." ALJ Ex. 1, at 3 (No. 15–7).

In addition, the Superior I Order alleged that the pharmacy "failed to create and maintain accurate [schedule II order forms] in violation of 21 U.S.C. 842(a)(5)," and that "[a]t least two [of its] pharmacists . . . shared a private key (password) for digitally signing" controlled substances orders, "in violation of 21 CFR 1311.30(a), (c), and (e)." ALJ Ex. 1, at 3–4 (No. 15–6). Finally, the Superior I Order alleged that a DEA audit for the period of May 2, 2011 through February 4, 2013 found, *inter alia,* that the pharmacy was short 15,560 dosage units (du) of oxycodone 30 mg; 11,951 du of hydromorphone 8 mg; 946 du of hydromorphone 4 mg; and 864 du of methadone 10 mg. *Id.* at 4.

The Superior II Order alleged that it had also failed to maintain accurate schedule II order forms and had failed to retain copy three of these forms as required by DEA regulations. ALJ Ex. 1, at 3 (No. 15–7) (citing 21 CFR 1305.13(a) & (e); *id.* § 1305.17(a); 21 U.S.C. 827(b)). The Order further alleged that the pharmacy failed to create records of the quantity and date received for orders it placed using the Controlled Substances Ordering System (CSOS) and that it "also failed to electronically archive and link these records to the original order." *Id.* at 4. Finally, the Superior II Order alleged that a DEA audit for the period of July 31, 2012 through February 4, 2013 found, *inter alia,* that the pharmacy had overages of 2,576 du of hydromorphone 8 mg; 1,189 du of oxycodone 30; and 896 du of methadone 10 mg.

The Show Cause Order issued to Superior I was served on October 17, 2014, and the Show Cause Order issued to Superior II was served on October 16, 2014. *See* ALJ Ex. 3 (No. 15–6); ALJ Ex. 4 (No. 15–7). On November 14, 2014, each pharmacy, through its counsel, requested a hearing on the allegations. *See* ALJ Ex. 2 (No. 15–6); ALJ Ex. 3 (No. 15–7). Each matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge (ALJ) Christopher B. McNeil.

The Prehearing Motions and Rulings

On December 3, 2014, the ALJ issued an Order for Prehearing Statements and Setting the Matter for Hearing (hereinafter, Prehearing Order) in each case. *See* ALJ Ex. 5 (No. 15–6); ALJ Ex. 6 (No. 15–7). In each Prehearing Order, the ALJ directed the Government to file its Pre-hearing Statement no later than 2 p.m. on December 22, 2014, and each Respondent to file its Prehearing Statement no later than 2 p.m. on January 5, 2015. ALJ Ex. 5, at 1 (No. 15–

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[1] With respect to Superior I, the Show Cause Order stated the red flag as "individuals paying high prices for prescriptions for controlled substances with cash." ALJ 1, at 2 (No. 15–6).

6); ALJ Ex. 6, at 1 (No. 15–7). The Orders also directed the parties to "[p]rovide the names and current addresses of all witnesses whose testimony is to be presented," and that "[i]f the Respondent's corporate representative intends to testify, the representative must be listed, and a summary of anticipated testimony as described below must be provided." ALJ Ex. 5, at 2 (No. 15–6); ALJ Ex. 6, at 2 (No. 15–7). The ALJ's Orders provided the following instruction regarding the summaries of testimony:

> Provide a brief summary of the testimony of each witness, with counsel for the Government to indicate clearly each and every act, omission or occurrence upon which it relies in seeking to revoke the Respondent's Certificate of Registration, and counsel for Respondent to indicate clearly each and every matter as to which Respondent intends to introduce evidence in opposition. The summaries are to state what the testimony will be, rather than merely listing the areas to be covered. The parties are reminded that testimony not disclosed in the prehearing statements or pursuant to subsequent rulings is likely to be excluded at the hearing.

ALJ Ex. 5, at 2 (No. 15–6); ALJ Ex. 6, at 2 (No. 15–7).

The ALJ's Orders also provided that "[a]ny requests for subpoena[s] are to be filed by 2:00 p.m. E.S.T. on January 12, 2015," and that "[s]ubpoena requests that do not comply with these instructions will be returned to the requestor without further action." [2] ALJ Ex. 5, at 4 (No. 15–6); ALJ Ex. 6, at 4 (No. 15–7). The ALJ's Orders further provided that "[w]henever a party seeks to file any document, motion, exhibit or otherwise communicate in writing with the Administrative Law Judge, the party must provide a true copy of the same to the opposing party, using the contact information shown in the Certificate of Service below . . . [and] [t]he party making such a filing shall include a 'Certificate of Service' stating that a true copy of the submission has been provided to the opposing party, and shall specify the means by which" this was accomplished. ALJ Ex. 5, at 5–6 (No. 15–6); ALJ Ex. 6, at 5–6 (No. 15–7).

Finally, the ALJ's Orders directed the parties to file their proposed exhibits with his Office no later than 2:00 p.m. on January 12, 2015; it also directed that a copy of the exhibits be served on the opposing party. ALJ Ex. 5, at 2 (No. 15–6); ALJ Ex. 6, at 2 (No. 15–7). The ALJ's Orders further directed that "[w]hen any party seeks to . . . present proposed exhibits," the party must "timely provid[e] the OALJ with a facsimile copy" and "must mail hard copy filings sufficiently in advance of the due date to assure timely receipt by the hearing clerk" as well as "that documents are to be filed in triplicate." ALJ Ex. 5, at 5–6 (No. 15–6); ALJ Ex. 6, at 5–6 (No. 15–7).

In his Orders, the ALJ also noted that the cases appeared to "involve common questions of law or fact" and thus directed the parties to address whether they should be consolidated. ALJ Ex. 5, at 3 (No. 15–6); ALJ Ex. 6, at 3 (No. 15–7). Thereafter, the Government moved to consolidate the cases (as well as two other cases). Respondent opposed the Government's motion.

On December 22, 2014, the Government filed its Prehearing Statements with respect to each pharmacy. In each of these, the Government disclosed that it intended to elicit testimony from an expert regarding his review of "numerous controlled substance prescriptions filled by Respondent that contained one or more red flags for diversion which Respondent never resolved." ALJ Ex. 6, at 3 (No. 15–6); ALJ Ex. 8, at 3–4 (No. 15–7). The Government then identified the same set of seven red flags. ALJ Ex. 6, at 3 (No. 15–6); ALJ Ex. 8, at 3–4 (No. 15–7). With respect to both pharmacies, the Government then set forth the expert's proposed testimony regarding various oxycodone 30 mg prescriptions and the red flags they presented, as well as his proposed testimony regarding the pharmacy's dispensing of large quantities of hydromorphone and the red flags they presented. ALJ Ex. 6, at 4 (No. 15–6); ALJ Ex. 8, at 3–4 (No. 15–7). And with respect to Superior I, the Government also disclosed that the expert "will also testify about a customer who willingly purchased a prescription for oxycodone . . . that costs 37% more than the same prescription four months earlier," and "that this fact, combined with the fact that the prescription was facially invalid [as it contained] no patient address constituted a red flag for diversion." ALJ Ex. 6, at 5 (No. 15–6).

The Government then noticed both Respondents that its expert "will testify that the facts surrounding the prescriptions listed above constituted red flags for diversion and that there is no evidence that any of the red flags were resolved prior to distributing the controlled substances to the customers." *Id.* at 3 (No. 15–6). Finally, it noticed Respondents that its expert "will testify that . . . Respondent[s'] pharmacists failed to exercise their corresponding responsibility to ensure that prescriptions for controlled substances were issued for a legitimate medical purpose in the usual course of professional practice." ALJ Ex. 6, at 3 (No. 15–6); ALJ Ex. 8, at 3–4 (No. 15–7).

On January 5, 2015, each Respondent filed a "Motion to Compel" and a "Motion for Enlargement of Time to File . . . Pre-hearing Statement," as well as a Prehearing Statement. ALJ Exs. 9, 10, 11 (No. 15–6); ALJ Exs. 9, 10, 12 (No. 15–7). In their Motions to Compel, each Respondent noted that on February 4, 2013, DEA had executed an Administrative Inspection Warrant at it and sought an Order from the ALJ requiring the Government to disclose the documents and testimony submitted by DEA Investigators to the Federal Magistrate Judge in obtaining the Warrants. ALJ Ex. 10, at 2 (No.15–6); ALJ Ex 10, at 2 (No. 15–7). Each Respondent's Motion to Compel also sought to require the Government to: (1) Provide "full and complete copies of all computer data seized . . . during the execution of the" warrant; (2) identify "all DEA personnel involved in the preparation and execution of the [warrant] and the subsequent review and analysis of the information, records, and data seized"; and (3) provide "reports of, and the substance of, any statements made to DEA investigators by [Respondent's] staff." ALJ Ex. 10, at 5 (No.15–6); ALJ Ex 10, at 5 (No. 15–7).

Each Respondent also sought an extension of the time to file its Prehearing Statement to the end of March 2015 and sought to reschedule the hearing "to no sooner than June 2015." ALJ Ex. 11, at 3 (No. 15–6); ALJ Ex. 9 (No. 15–7). As support for the motions, Respondents argued that since the execution of the warrants, the Government had 20 months to review the records, and that "[d]uring this time, the information was not available to Respondent." ALJ Ex. 11, at 3 (No. 15–6); ALJ Ex. 9, at 3 (No. 15–7). Respondents further argued "[w]hile a portion of the seized information, most notably the prescriptions, was provided to Respondent[s] in electronic format, the sheer volume of information coupled with the unreasonably short deadlines surrounding the holiday season make analysis of the information by [it] impossible." ALJ Ex. 11, at 3 (No. 15–6); ALJ Ex. 9, at 3 (No. 15–7). Respondents further argued that "due process requires, and good cause exists, for a significant" extension of the time to file the Prehearing Statements and "to prepare for a lengthy hearing in" these matters. ALJ Ex. 11, at 3 (No. 15–6); ALJ Ex. 9, at 3 (No. 15–7).

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[2] The Order further required that "[a]ny motion to quash a subpoena must be filed within three working days of receipt of the subpoena request and must be served on the opposing party." ALJ Ex. 5, at 4–5 (No. 15–6); ALJ Ex. 6, at 4–5 (No. 15–7).

The Government opposed these motions. With respect to the Motions to Compel, the Government argued that in its Prehearing Statements, it had provided a summary of the testimony it intended to elicit as well as a list of the exhibits it intended to offer; the Government also noted that several weeks earlier, it had met with one of Respondents' counsels and that at no time then or since its motion, had Respondents' counsel "communicate[d] a need for, or request[ed] any" of the information it sought through the motions. ALJ Ex. 16, at 3 (No. 15–7). The Government further argued that it had fully complied with its disclosure obligations, and that to the extent Respondents were seeking discovery, " '[t]here is . . . no general right to discovery under either the APA or DEA regulations, but rather only a limited right to receive in advance of the hearing the documentary evidence and summaries of the testimony which the Government intends to rely upon.' " ALJ Ex. 16, at 4 (No. 15–7) (quoting *Roy E. Berkowitz*, 74 FR 36758, 36760 (2009)). Finally, the Government argued that to the extent Respondents were asserting that they had a right to receive these materials as a matter of due process, "Respondent[s] ha[d] not even articulated how the requested materials might be relevant to this proceeding." ALJ Ex. 16, at 5 (No. 15–7).

Each Respondent filed a Reply to [the] Government's Response to Motion to Compel. ALJ Ex. 27 (No. 15–6); ALJ Ex.18 (No. 15–7). Therein, Respondents contended that they were entitled to the documents as a matter of due process because the Government had represented that one of its proposed witnesses (a Diversion Investigator) would testify regarding his/her interviews with Respondents' staff and that they would be prejudiced if the Government did not provide the "same." ALJ Ex. 27, at 2 (No. 15–6); ALJ Ex. 18, at 2 (No. 15–7). Respondents further asserted that the "information is essential," because the Government intended to put on evidence that the prescriptions raised red flags and that "Respondent[s] fail[ed] to exercise [their] corresponding responsibility to resolve the 'red flag[s],' " and the Government "has not identified one patient or doctor related to the prescriptions allegedly containing unresolved red flags." ALJ Ex. 27, at 2 (No. 15–6); ALJ Ex. 18, at 2 (No. 15–7).

The Government also opposed Respondents' Motions for Enlargement of Time. ALJ Ex. 16, at 6 (No. 15–7). The Government argued that the Show Cause Orders and Prehearing Statements had "specifically outlined" the allegations, "as well as the approximate number of documents it intend[ed] to introduce into evidence." *Id.* The Government further argued that it was "patently specious" for Respondents "[t]o characterize this matter as something much more voluminous and complicated than what it is and, as a result, argue that further delay is necessary." *Id.* The Government also contended that to the extent Respondents were seeking an extension to review records and prescriptions beyond those referenced in the Show Cause Orders and its Prehearing Statements, those documents were not "material to the allegation that he [sic] unlawfully dispensed to customers identified in the OTSC and Government's Prehearing Statement." *Id.* at 6–7.

On January 5, 2015, the ALJ denied Respondents' Motions for Enlargement. ALJ Ex. 11, at 3 (No. 15–7); ALJ Ex. 12, at 4 (No. 15–6). The ALJ specifically noted "that since at least October 16, 2014, Respondent[s] ha[ve] been informed of the nature of the charges presented in the Order to Show Cause," and that in their motions, Respondents had acknowledged that the Government had provided them with the prescriptions. ALJ Ex. 11, at 3 (No. 15–7); ALJ Ex. 12, at 3 (No. 15–6). The ALJ explained that neither Respondent had "established that it has been prevented from evaluating those prescriptions identified in the Order to Show Cause [or] that it has been prevented from preparing its prehearing statement." ALJ Ex. 11, at 3 (No. 15–7); ALJ Ex. 12, at 3 (No. 15–6). The ALJ also explained that Respondents had known since the issuance of his Prehearing Orders that they were required "to object to any term of that Order by not later than December 10, 2014," and that they failed to object to the orders until the day their Prehearing Statements were due. ALJ Ex. 11, at 3 (No. 15–7); ALJ Ex. 12, at 3 (No. 15–6). The ALJ thus concluded that:

> I am compelled to consider the nature of the allegations, which if proved suggest Respondent[s'] ability to fill controlled substance prescriptions would be inconsistent with the public interest. I am further compelled to consider Respondent[s'] own role in attempting to delay th[ese] proceeding[s], given that [they] failed to timely object to the deadlines set forth in the Order[s]. I am further compelled to consider fairness to all parties, and the convenience of witnesses now identified by the Government in its timely prehearing statement[s]. I am further compelled to consider the need for orderly and prompt administration of justice. All of these considerations compel my finding that good cause has not been shown for either enlarging the time for Respondent[s] to file [their] prehearing statement[s], or for continuing the hearing now set to being on January 27, 2015.

ALJ Ex. 11, at 3 (No. 15–7); ALJ Ex. 12, at 3 (No. 15–6).

The same day (according to OALJ date stamps), each Respondent filed its Prehearing Statement. ALJ Ex. 9 (No. 15–6); ALJ Ex. 12 (No. 15–7). Each Respondent proposed as witnesses "[a]ny and all patients whose prescriptions were seized . . . pursuant to the Administrative Inspection Warrant executed [on] February 4, 2013 or whose prescriptions for controlled substances were dispensed between January 1, 2011 and February 4, 2013." ALJ Ex. 9, at 3 (No. 15–6); ALJ Ex. 12, at 3 (No. 15–7). Respondent Superior I further attached a list of 2,355 purported patients, ALJ Ex. 9, at Attachment A (No. 15–6); and Respondent Superior II attached a list of 2,253 purported patients. ALJ Ex. 12, at Attachment A (No. 15–7). As for the required summary of anticipated testimony, each Respondent proposed that:

> These patients will each be asked to provide testimony regarding their medical history, injuries and related pathology, interactions with treating physicians and dispensing pharmacists, effectiveness of the prescribed controlled substances, continuity of treatment, their reasons for patronage of Superior Pharmacy, LLC . . . such other testimony relevant to the Government's allegation that any of these prescriptions raised 'red flags' which should have caused pharmacists to refuse to dispense the prescribed controlled substances.

ALJ Ex. 9, at 4 (No. 15–6); ALJ Ex. 12, at 4 (No. 15–7).

Respondents further proposed as witnesses "[a]ny and all physicians who issued the prescriptions seized . . . pursuant to the Administrative Inspection Warrant[s] . . . or whose prescriptions for controlled substances were dispensed at [them] between January 1, 2011 and February 4, 2013," as well as "[a]ny and all physicians who issued prescriptions for controlled substances to the patients identified . . . above after February 4, 2013." ALJ Ex. 9, at 3 (No. 15–6); ALJ Ex. 12, at 3 (No. 15–7). Each Respondent attached a list of several hundred physicians who had purportedly issued the controlled substance prescriptions dispensed by them. ALJ Ex. 9, at Attachment B (No. 15–6); ALJ Ex. 12, at Attachment B (No. 15–7). As for the anticipated testimony of the physicians, Respondents represented that:

> These physicians will confirm they performed adequate and appropriate physical examinations of the patients to whom they

> issued prescriptions for controlled substances, communication with the dispensing pharmacies regarding such prescriptions, the reasonableness and necessity of the prescriptions to control the pain or other complaints of their patients as required by the standard of care and Florida statutes.

ALJ Ex. 9, at 4 (No. 15–6); ALJ Ex. 12, at 4 (No. 15–7).

Next, Respondents proposed as witnesses "[a]ny and all pharmacists who dispensed prescriptions for controlled substances to the patients identified . . . above *after* February 4, 2013." ALJ Ex. 9, at 3 (No. 15–6); ALJ Ex. 12, at 3 (No. 15–7) (emphasis added). As for their anticipated testimony, Respondents represented that "[t]hese pharmacists will describe the information they obtained from the patients, physicians and other sources in order to resolve 'red flags,' if any, raised by the described prescriptions for controlled substances." ALJ Ex. 9, at 5 (No. 15–6); ALJ Ex. 12, at 5 (No. 15–7). Respondent did not, however, provide the names of any of the pharmacists. ALJ Ex. 9, at 3 (No. 15–6); ALJ Ex. 12, at 3 (No. 15–7).

Respondents also proposed as a witness Mr. Sam Badawi, a pharmacist and attorney. ALJ Ex. 9, at 3 (No. 15–6); ALJ Ex. 12, at 3 (No. 15–7). As for Mr. Badawi's anticipated testimony, Respondents represented that he:

> will testify regarding his qualifications as an expert in the field of pharmacy and the legal and ethical responsibilities of the pharmacists dispensing prescriptions at [each Respondent], the procedures used at [each Respondent] to consider and resolve 'red flags,' inventory, ordering and CSOS compliance issues. Mr. Badawi will further testify that he had reviewed the prescriptions at issue, the relevant inventory and ordering records and prepared summaries of the prescription dispensing activity at [each pharmacy] during 2011 and 2012, and identified significant errors in the inventory performed by the DEA.

ALJ Ex. 9, at 6 (No. 15–6); ALJ Ex. 12, at 6 (No. 15–7).

Respondents further proposed as a witness Mr. Jack Crowley of Gates Healthcare Associates. Respondents represented that Mr. Crowley:

> will testify regarding his knowledge and experience in the investigation, preparation and execution of Administrative Inspection Warrants and the subsequent investigation required. [He] will testify regarding errors in the audits performed by the agents/investigators involved in the investigation of [Respondents]. [He] reviewed the prescriptions, inventory and CSOS records of [Respondents]. [He] will further testify regarding [Respondents'] procedure[s] for resolving potential 'red flag' issues and compliance with recordkeeping requirements related to inventory records, DEA–222 order forms and CSOS issues.

ALJ Ex. 9, at 5 (No. 15–6); ALJ Ex. 12, at 5 (No. 15–7).[3]

On January 9, 2012, each Respondent filed a motion to enlarge the time for filing its proposed exhibits or to alternatively provide its proposed exhibits electronically, as well as a motion to enlarge the time to file its requests for subpoenas. ALJ Ex. 22 (No. 15–6); ALJ Ex. 23 (No. 15–7). In its motion, Superior I explained that its "Prehearing Statement identifies four categories of proposed exhibits which consist of 23,032 documents," of which "20,925 pages represent the documents seized, and provided to Respondent electronically, by the DEA." ALJ Ex. 22, at 2 (No. 15–6). Superior I explained that to comply with the ALJ's Prehearing Order, which required that three copies of each exhibit be filed with the OALJ and one copy be filed with opposing counsel, this would require more than 92,000 pages and "approximately nineteen standard boxes of paper, which is approximately 950 pounds." *Id.* Superior I further explained that because of the volume of copying needed to comply with the Prehearing Order, the documents would have to be sent "to a third party for reproduction" and "the reproduction cannot be completed in the allotted time." *Id.* at 3. As for its subpoena requests, Superior I contended that the ALJ's Prehearing Order was ambiguous "as to whether the requests and completed subpoenas are to be filed in triplicate with the Hearing Clerk," and because it was seeking to subpoena 2,861 witnesses, it "cannot complete the . . . requests . . . with the completed subpoenas using the required template in the allotted time." *Id.*

Superior II made similar assertions to Superior I, noting that its proposed exhibits "consist of 32,123 documents," of which "30,441 pages represent the documents seized, and provided to [it] electronically, by the DEA," and that to comply with the ALJ's Prehearing Order, it would have to provide more than 128,000 pages of documents, and require "approximately 1,300 pounds" of paper. ALJ Ex. 23, at 2 (No. 15–7). As did Superior I, Superior II asserted that it would have to use a third-party to perform the necessary copying, which could not "be completed in the allotted time." *Id.* at 3. Superior II also asserted that it could not complete the 2,549 subpoena requests for its proposed witnesses on time. *Id.*

On January 12, 2015, each Respondent submitted a letter (dated Jan. 9) to the Hearing Clerk along with thumb drives which contained "the images of each of the exhibits in [its] Prehearing Statement." ALJ Ex. 24 (No. 15–6); ALJ Ex. 24 (No. 15–7). Each Respondent's letter also advised that the paper copies of the subpoena requests would be hand delivered on Monday, January 12, 2015, and on that date, the ALJ "received more than 3,000 written requests for the issuance of subpoenas in the[] two cases." Tr. 18; *see also* ALJ Ex. 24 (No. 15–6); ALJ Ex. 24 (No. 15–7). According to the ALJ, neither Respondent provided "a certificate of service establishing that [they] ha[d] provided the Government with a true copy of these requests." Tr. 18.

The same day, the ALJ's Law Clerk sent a letter under his own signature to each Respondent's Counsel noting that the OALJ had received the thumb drives. ALJ Ex. 28 (No. 15–6); ALJ Ex. 28 (No. 15–7). The Law Clerk then explained that he was returning the thumb drives to each Respondent's counsel because "[t]he submission of the thumb drive does not adhere to the" ALJ's Prehearing Order of December 3, 2014. ALJ Ex. 28 (No. 15–6); ALJ Ex. 28 (No. 15–7).

On January 12, the ALJ denied each Respondent's Motion to Compel. The ALJ noted that in the case of *Edge Pharmacy* (Docket No. 15–3), the respondent had sought to compel the disclosure of much of the same material as sought by Superiors I and II. ALJ Ex. 29, at 4 (No. 15–6); ALJ Ex. 29, at 4 (No. 15–7). The ALJ further noted that in *Edge,* the Chief Administrative Law Judge (CALJ) had denied the motion of the respondent on the ground that it did "not comport with the narrowly-focused grant of authority in 21 CFR 1316.52(d)," and that the respondent did "not seek to compel . . . the class of documents discoverable under the [Administrative Procedure Act] or subject to inspection under DEA regulations." ALJ Ex. 29, at 4 (No. 15–6); ALJ Ex. 29, at 4 (No. 15–7). As for the reports and the substance of any statements made by Respondents' staff to the Agency's Investigators, the ALJ also found that the CALJ's reasoning applied to these materials. ALJ Ex. 29, at 4 (No. 15–6); ALJ Ex. 29, at 4 (No. 15–7). The ALJ thus concluded that each Respondent had failed to establish its entitlement to the documents. ALJ Ex. 29, at 4 (No. 15–6); ALJ Ex. 29, at 4 (No. 15–7).

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[3] Respondents also proposed as witnesses each person "who participated in the preparation of the application for the Administrative Inspection Warrant[s]," as well as each person "who participated in the execution of the Administrative Inspection Warrant[s]." ALJ Ex. 9, at 3–4 (No. 15–6); ALJ Ex. 12, at 3–4 (No. 15–7).

The same day, in the Superior I matter, the Government submitted its request for the issuance of subpoenas for four witnesses, and in the Superior II matter, the Government submitted its request for the issuance of subpoenas for five witnesses, all of whom had been previously identified in the respective Prehearing Statement.[4] ALJ Ex. 25, at 1–2 (No. 15–6); ALJ Ex. 25, at 1–2 (No. 15–7). The Government also submitted its proposed exhibits in each matter. Docket Sheet, at 2 (No. 15–6); Docket Sheet, at 2 (No. 15–7).

The Government's Motions To Consolidate

On January 13, 2015, the Government moved to consolidate the cases, along with a third matter (Jet Pharmacy). ALJ Ex. 31 (No. 15–6); ALJ Ex. 31 (No. 15–7). In its motions, the Government argued that there were common issues of law and fact with respect to the pharmacies, noting that it intended to call the same expert in each of the cases and each Respondent had stated that it intended to call the same two experts. ALJ Ex. 31, at 2–3 (No. 15–6); ALJ Ex. 31, at 2–3 (No. 15–7). The Government further argued that the expert's testimony would "account for the bulk of the Government's and likely the Respondents' cases in terms of length of testimony," and that consolidation would "result in a tremendous conservation of time and resources by allowing the Government to present its expert's testimony in one proceeding rather than in three separate proceedings." ALJ Ex. 31, at 5 (No. 15–6); ALJ Ex. 31, at 5 (No. 15–7).

The Government also argued that, although "each of the Respondent pharmacies is a separate business entity, there are also strong indications of common ownership, management, and/or control between the Respondents," and that Superior I and II "are both owned and operated by Victor Obi-Anadiume."[5] ALJ Ex. 31, at 3 (No. 15–6); ALJ Ex. 31, at 3 (No. 15–7). As support for this assertion, the Government attached to its motions various documents it obtained from the Florida Department of Heath showing that Victor Obi owned both Superior I and II. The Government thus maintained that consolidation was warranted "because the conduct of one Respondent may be imputed to other Respondents if it can be shown that the same individuals responsible for misconduct at one pharmacy also managed and/or controlled other pharmacies." ALJ Ex. 31, at 5 (No. 15–6); ALJ Ex. 31, at 5 (No. 15–7).

Each Respondent filed identical oppositions to the Government's motions. *See* ALJ Ex. 30 (No. 15–6); ALJ Ex. 32 (No. 15–7). Therein, Respondents argued that "it is not . . . sufficient for two (2) actions to have a common defendant or one common issue of law" and that "other considerations are necessary such as whether maintaining separate actions would lead to inconsistent rulings on similar issues of fact and law and to ensure that the same standard is applied to the determination of such issues as they arise in each case." ALJ Ex. 30, at 3–4 (No. 15–6); ALJ Ex. 32, at 3–4 (No. 15–7) (citation omitted). Respondents also argued that consolidation of the cases "may cause unnecessary confusion for the fact finder and prejudice to the parties." ALJ Ex. 30, at 4 (No. 15–6); ALJ Ex. 32, at 4 (No. 15–7) (citation omitted).

Respondents then maintained that "because each prescription represents a different pattern of facts, it appears there is no overlapping factual issue between the two matters," and "[a]s such, there is no risk of inconsistent results" which would support consolidation. ALJ Ex. 30, at 5 (No. 15–6); ALJ Ex. 32, at 5 (No. 15–7). Respondents further maintained that "there is a high risk that one defendant could be prejudiced by evidence relating to another defendant." ALJ Ex. 30, at 5 (No. 15–6); ALJ Ex. 32, at 5 (No. 15–7). Respondents also asserted that consolidation would not promote judicial economy "[b]ecause of the large number . . . and limited overlap of" the witnesses and because "the time necessary to complete the hearing as to both parties could exceed ninety (90) days." ALJ Ex. 30, at 6 (No. 15–6); ALJ Ex. 32, at 6 (No. 15–7).

On January 15, 2015, each Respondent filed a further pleading, which appear to be identical, on the issue of consolidation. ALJ Ex. 40 (No. 15–6); ALJ Ex. 40 (No. 15–7). In addition to the arguments they previously raised, Respondents contended that "[t]o the extent the government seeks to rely on a single expert to prove its case in all three matters, it heightens the risk of confusion or attempts to conflate issues between three distinct defendants." ALJ Ex. 40, at 6 (No. 15–6); ALJ Ex. 40, at 6 (No. 15–7). They also argued that "although Respondent[s] share Mr. Obi as a common owner, [he] is not responsible for the day-to-day operations or the implementation of policies and procedures at these separate businesses" as each pharmacy had a "different pharmacy manager[ ]." ALJ Ex. 40, at 7 (No. 15–6); ALJ Ex. 40, at 7 (No. 15–7). Respondents further contended that "Mr. Obi did not dispense medication or otherwise process prescriptions at these pharmacies during all relevant time periods described in the Orders to Show Cause." ALJ Ex. 40, at 7 (No. 15–6); ALJ Ex. 40, at 7 (No. 15–7).

On January 21, 2015, the ALJ granted the Government's motions with respect to Superior I and Superior II. ALJ Ex. 1 (No. 15–6 & 15–7). The ALJ specifically found that "the Government ha[d] demonstrated the presence of common questions of law and fact with respect to Superior I and Superior II, and ha[d] shown the need to take steps to avoid unnecessary cost or delay." *Id.* at 7. More specifically, the ALJ found that the Show Cause Orders "set forth substantially similar factual claims" in that "pharmacists at both pharmacies dispensed controlled substances under conditions where the pharmacists knew or should have known that the controlled substances were being either diverted or abused by those who received the substances." *Id.* The ALJ further found that "[i]n both cases, the [Government] alleged the pharmacists filled prescriptions notwithstanding red flags relating to the unusual distance the patients traveled to have their prescriptions filled, and notwithstanding red flags relating to evidence that the patients were filling multiple prescriptions which bore no address for the patients." *Id.*

The ALJ also rejected Respondents' contention that there was "a substantial risk of prejudice to Respondents in either case." *Id.* at 8. The ALJ specifically found that "the prospect of hearing from the fact and expert witnesses in both cases will reduce the risk of inconsistencies like those that could arise through separate hearings." *Id.* The ALJ also "expressly rejected" Respondent's contention that there was a heightened "risk of confusion" because the Government intended to use the same expert to prove its case, explaining that "[o]ne expert can easily address the conduct attributed to pharmacists working at these two pharmacies." *Id.* Finally, the ALJ reasoned that "[g]iven there is at least some showing of common ownership, the Government should be, and will be, permitted to advance its theory that 'the conduct of one Respondent may be imputed to [the] other Respondent[ ] if it can be shown that the same individuals responsible for misconduct at one pharmacy also managed and/or controlled other pharmacies.'" *Id.* (citation omitted). The ALJ thus ordered that the cases against Superior I and

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[4] The Government also served a copy of both subpoena requests on each Respondent. ALJ Ex. 25, at 2 (No. 15–6); ALJ Ex. 25, at 2 (No. 15–7).

[5] Mr. Obi-Anadiume is also referred to as Mr. Obi throughout this decision.

Superior II be consolidated under Docket No. 15–6. *Id.*

The Government's Motions *in Limine*

On January 15, 2015, the Government also filed a Motion *in Limine* in each matter. Therein, the Government argued that Respondents had failed to comply with the ALJ's Pre-hearing Orders in that they failed to provide adequate summaries of the testimony of their proposed witnesses. With respect to Mr. Badawi, Respondents' proposed expert in pharmacy practice, the Government argued that Respondents' Prehearing Statements "state[d] no facts or conclusions which, if proven, would rebut any allegations that the Government has made in its OTSC[s] or Prehearing statement[s]." ALJ Ex. 36, at 4 (No. 15–6); ALJ Ex. 36, at 4–5 (No. 15–7). The Government specifically argued that while "Respondent[s] state[d] that Mr. Badawi ha[d] 'prepared summaries' of prescription activity and identified 'errors' in DEA inventory[,] [they] fail[ ] to disclose what those summaries entail or what errors have been discovered." ALJ Ex. 36, at 4–5 (No. 15–6); ALJ Ex. 36, at 5 (No. 15–7). The Government further argued that Respondents had "also failed to identify a single 'procedure used at [the pharmacies] to consider and resolve alleged 'red flags,' inventory, ordering and CSO[S] compliance issues." ALJ Ex. 36, at 5 (No. 15–6); ALJ Ex. 36, at 5 (No. 15–7). The Government also argued that "notably absent from [the] Prehearing Statement[s] is any notice that Mr. Badawi will opine that any of the prescriptions identified in the [Show Cause Orders] and the Government's Prehearing Statement[s] were issued in compliance with federal or state law." ALJ Ex. 36, at 5 (No. 15–6); ALJ Ex. 36, at 5 (No. 15–7).

As for Respondents' disclosures pertaining to the testimony of Mr. Crowley, the Government argued that "no facts [were] proffered to give [it] any notice regarding [his] conclusions regarding audit errors, or the basis for those conclusions, should they exist." ALJ Ex. 36, at 5 (No. 15–6); ALJ Ex. 36, at 5 (No. 15–7). The Government also argued that while Respondents proposed that this witness would testify regarding their procedures for resolving red flags and complying with other requirements, Respondent had not "offer[ed] a single fact or detail to describe, identify, or explain that procedure." ALJ Ex. 36, at 5 (No. 15–6); ALJ Ex. 36, at 5 (No. 15–7). The Government further contended that it is unclear whether this witness's proposed testimony would discuss the procedures in place during the period of the alleged misconduct or as to procedures subsequently instituted. ALJ Ex. 36, at 6 (No. 15–6); ALJ Ex. 36, at 6 (No. 15–7). Finally, the Government argued that Respondents' disclosure was "void of any detail about the information [this witness] reviewed to form his opinions about the DEA audits or the procedures Respondents employed at their pharmacy." ALJ Ex. 36, at 6 (No. 15–6); ALJ Ex. 36, at 6 (No. 15–7).

Addressing Respondents' proposed taking of the testimony of the numerous patients who filled controlled substance prescriptions at Respondents, the Government maintained that Respondents' disclosure "constitute[d] a wholesale failure to describe 'each and every matter as to which [they] intend[ed] to introduce evidence in opposition,'" as required by the ALJ's Pre-hearing Order. ALJ Ex. 36, at 6 (No. 15–6); ALJ Ex. 36, at 6 (No. 15–7). As for the physicians who wrote the prescriptions, the Government argued that the disclosures were inadequate because "Respondent[s] merely indicate[ ] that these unknown individuals will testify regarding 'communication[s] with the dispensing pharmacists regarding such prescriptions," and "no facts about any such communications are revealed."[6] ALJ Ex. 36, at 6 (No. 15–6); ALJ Ex. 36, at 6 (No. 15–7).

The Government also contended that testimony and documentation regarding prescriptions which it did not intend to offer into evidence was irrelevant. ALJ Ex. 36, at 8 (No. 15–6) ALJ Ex. 36, at 8 (No. 15–7). Finally, with respect to the physicians who issued prescriptions filled by Respondents after February 4, 2013 and the pharmacists who filled the prescriptions, the Government argued that Respondent had not even identified these persons and that their proposed testimony was "stated only in general terms [and] lack[ed] conclusions." ALJ Ex. 36, at 7 (No. 15–6); ALJ Ex. 36, at 7 (No. 15–7).

In its motion, the Government also addressed Respondents' use of a thumb drive to provide its exhibits. ALJ Ex. 36, at 3 (No. 15–6); ALJ Ex. 39, at 3 (No. 15–7). According to the Government, the thumb drive contained "hundreds of different files, which contain, collectively, thousands of pages of documents," of which only one file, which "consist[ed] of 1490 pages," "appeared to be marked for identification." ALJ Ex. 36, at 3–4 (No. 15–6); ALJ Ex. ALJ Ex. 36, at 3–4 (No. 15–7). The Government further stated that the other files were "neither marked for identification nor paginated." ALJ Ex. 36, at 4 (No. 15–6); ALJ Ex. 36, at 4 (No. 15–7). The Government argued that Respondents' submission of their proposed documentary evidence did not "comply with the ALJ's order in terms of labeling and form." ALJ Ex. 36, at 8 (No. 15–6); ALJ Ex. 36, at 8 (No. 15–7). The Government also argued that because "none of [Respondents'] summarized testimony reference[d] any particular documents or page, [it was] unable to ascertain whether any of the documents . . . would be relevant to [the] proceeding." ALJ Ex. 36, at 9 (No. 15–6); ALJ Ex. 36, at 9 (No. 15–7).

On January 21, 2015, each Respondent filed a Response to the Government's Motion; as with Respondents' other filings, the Responses appear to be identical. *Compare* ALJ Ex. 53 (No. 15–6) *with* Response to Government's Motion *In Limine* (No. 15–7) (hereinafter, Superior II Response to Motion *in Limine*).[7] Therein, Respondents argued that the Government's Motions were "completely devoid of intellectual integrity" because the Government's Prehearing Statement "fail[ed] to specifically identify a single prescription or patient and only generally refers to areas of discussion of its witnesses," including the proposed testimony of its expert witness. ALJ Ex. 53, at 2 (No. 15–6); Superior II Response to Motion *in Limine,* at 2. Respondents also argued that "[t]he Government's Prehearing Statement only identifies two patients by their initials and only one by the alleged city of residence." ALJ Ex. 53, at 3 (No. 15–6); Superior II Response to Motion *in Limine,* at 3.[8] Respondents thus contended that the Government provided an "inadequate description of the testimony concerning specific patients and prescriptions," and that they were "placed under extreme prejudice in [their] preparation for this expedited hearing." ALJ Ex. 53, at 3 (No.

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[6] Respondents did, however, disclose the names of the physicians as part of their Prehearing Statements. Respondents also stated that they intended to elicit testimony from the physicians "confirm[ing] [that] they performed adequate and appropriate physical examinations of the patients," as well as testimony as to "the reasonableness and necessity of the prescriptions to control the pain or other complaints of their patients as required by the standard of care and Florida statutes." ALJ Ex. 9, at 4 (No. 15–6); ALJ Ex. 12, at 4 (No. 15–7).

[7] While this filing is part of the record, it was not assigned an ALJ Exhibit Number and is not included on the list of ALJ Exhibits in the Superior II matter.

[8] While this was true with respect to Superior I, the Government's Prehearing Statement in Superior II identified each of the patients whose prescriptions were at issue by their initials, and with respect to 13 of the patients, either the Prehearing Statement or the Show Cause Order identified the patient's city of residence. ALJ Ex. 1, at 2–3 (No. 15–7); ALJ Ex. 6, at 4–6 (No. 15–7).

15–6); Superior II Response to Motion *in Limine,* at 3. Respondents also disputed the Government's contention that their argument should be rejected because during a December meeting with Government Counsel, they did not ask for additional information regarding the patients' names. ALJ Ex. 53, at 3 (No. 15–6); Superior II Response to Motion *in Limine,* at 3.

Respondents further took issue with the Government's contention (with respect to both pharmacies) that only a small number of the thousands of persons listed in their Prehearing Statements were actually identified as patients. ALJ Ex. 53, at 2 (No. 15–6); Superior II Response to Motion *in Limine,* at 2. According to each Respondent, it listed all of the "patients whose prescriptions were dispensed and doctors who generated the prescriptions [that were] filled at the pharmacy during the relevant time period," because at the time it filed its Prehearing Statement, the Government was "the only party . . . to know which patients, doctors, and pharmacists are material and relevant to the allegations they chose to include in the" Show Cause Order. ALJ Ex. 53, at 3 (No. 15–6); Superior II Response to Motion *in Limine,* at 3. Respondents thus contend that "the potential exclusion of material and relevant witnesses as requested by the Government . . . would be arbitrary, capricious, and an abuse of discretion." ALJ Ex. 53, at 3–4 (No. 15–6); Superior II Response to Motion *in Limine,* at 3–4.

As for the Government's contention that Respondents had failed to disclose the proposed testimony of the patients, doctors and pharmacists with adequate specificity, Respondents argued that "without the identification of the prescriptions and/or patients at issue (as defined by the OSC), a specific summary of each and every potentially relevant witness is impossible within the timeframe provided." ALJ Ex. 53, at 6 (No. 15–6); Superior II Response to Motion *in Limine,* at 6. Continuing, Respondents argued that "[t]he witnesses will confirm their interaction with the pharmacists in resolving 'red flags' and verify the prescriptions were issued for a legitimate medical purpose in the usual course of professional practice." ALJ Ex. 53, at 6 (No. 15–6); Superior II Response to Motion *in Limine,* at 6. Notably, Respondents did not maintain that the pharmacists would testify that they resolved red flags.

As for the Government's attempt to bar the testimony of Mssrs. Badawi and Crowley, Respondents argued that they "ha[d] summarized [their] testimony to the same extent that the Government summarized its proposed testimony." ALJ Ex. 53, at 5 (No. 15–6); Superior II Response to Motion *in Limine,* at 5. Respondents appeared to argue that they could not offer more detail as to the testimony of these witnesses because they were "without notice of what specific facts and opinions [would] be offered in the Government's prima facie case as the Government chose to not disclose specifics." ALJ Ex. 53, at 6 (No. 15–6); Superior II Response to Motion *in Limine,* at 6.

As for the Government's attempt to bar their proposed documentary evidence, Respondents argued that they were "prejudiced by the Government's inadequate Prehearing Statement which forced Respondent[s] to incorporate and include all potential documents and witnesses from the relevant time period." ALJ Ex. 53, at 4 (No. 15–6); Superior II Response to Motion *in Limine,* at 4. Respondents further maintained that "[t]his prejudice would have only been exasperated [sic] by the costs associated with production of multiple sets of paper copies of the voluminous records." ALJ Ex. 53, at 4 (No. 15–6); Superior II Response to Motion *in Limine,* at 4. Respondents asserted that the electronic files were organized in four separate folders, and the folder which included the documents seized pursuant to the Administrative Inspection Warrant, was simply "a mirror copy, in the exact form, of the digital files *dumped* on Respondent by the DEA at the time of service of the Order to Show Cause." ALJ Ex. 53, at 4 (No. 15–6); Superior II Response to Motion *in Limine,* at 4. Respondents stated that they had no way of knowing whether folder three "represent[ed] all documents seized and/or reviewed by the Government"; they further argued that "the Government made no attempt to label and/or organize the material provided." ALJ Ex. 53, at 4 (No. 15–6); Superior II Response to Motion *in Limine,* at 4.

Concluding, Respondents argued that the Government had nearly two years to review the documents and that between February 4, 2013 (the date the AIWs were served) and the dates of service of the Show Cause Orders), "Respondent[s] had no access to these records." ALJ Ex. 53, at 5 (No. 15–6); Superior II Response to Motion *in Limine,* at 5. Respondents thus argued that to exclude their "proposed testimony and exhibits, based exclusively on circumstances created by the Government, would be an extreme abuse of discretion." ALJ Ex. 53, at 6 (No. 15–6); Superior II Response to Motion *in Limine,* at 6.

On January 27, 2015, the ALJ conducted the initial day of the hearing during which he addressed the Government's Motions *in Limine.*[9] With respect to the proposed testimony of the more than 5,000 patients who filled their prescriptions at Respondents, the ALJ granted the Government's Motions for two reasons. First, he found that Respondents had failed to comply with his Prehearing Order because they had "not described with sufficient detail the testimony of the proposed witnesses." ALJ Ex. 7, at 3 (No. 15–6/15–7) (Journal Entry and Order From Initial Day of Hearing). Second, he found that the proposed testimony of the patients "would not constitute relevant evidence, given the nature of the charges appearing in the Orders to Show Cause, as elaborated upon by the Government's Prehearing Statements. *Id.*

As for the proposed testimony of the physicians, the ALJ found that Respondents' Pre-hearing Statement did "not sufficiently identify the anticipated testimony of the witnesses, nor . . . make a sufficient showing that their testimony would constitute relevant evidence." *Id.* The ALJ further held that this ruling applied to both those physicians who filled the prescriptions before February 4, 2013, as well as after that date. *Id.* at 3–4. As to the latter category of physicians, the ALJ barred their testimony based on the additional reason that Respondents had not "timely identif[ied] by name the proposed witnesses," as again required by his Prehearing Order. *Id.* at 4. And the ALJ further barred Respondents from offering the testimony of "any pharmacists referred to but not identified in [their] prehearing statements." *Id.*

The ALJ also granted the Government's motion to exclude the testimony of Mssrs. Badawi and Crowley. As for Mr. Badawi, the ALJ found that Respondent had not complied with his Prehearing Order because "[u]nlike the articulation of specific red flags provided by the Government in its description of testimony for its expert, the Respondents' Prehearing Statements do not reveal the substance of this testimony, but instead presented only a list of areas to be discussed." *Id.* at 5. As for Respondents' representation that Mr. Badawi would also testify about errors he identified "in the inventory performed by the DEA," the ALJ found that Respondents failed to "articulat[e] the nature of these errors" and there was "[in]sufficient information regarding the timeframe used by Mr. Badawi to permit a determination that the testimony would be relevant." *Id.*

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[9] While the ALJ termed this day as the initial day of the hearing, he did not take any evidence. Tr. 1–36.

As for Mr. Crowley's proposed testimony regarding errors in the DEA audit, the ALJ found that Respondents "fail[ed] to articulate what those errors were." *Id.* And as for his proposed testimony "regarding procedures used by the pharmacies for resolving red flags and for complying with DEA recordkeeping requirements," the ALJ explained that he could not "discern from the summary of [his] testimony whether [it] concerns the practices of the pharmacies at the time of the execution of the administrative warrants, at times before then, or at the present time." *Id.* at 5–6. Finding that Respondents had "failed to comply with the prehearing order[s]" and had also "failed to establish that [his] proposed testimony would be relevant," the ALJ barred Mr. Crowley's testimony. *Id.* at 6.

The ALJ also addressed the Government's contention that Respondents' documentary evidence should be excluded. In his Order, the ALJ explained that in his Prehearing Orders he had directed the parties to exchange their exhibits on or before January 12, 2015, and that the "failure to timely do so would result in the exclusion of the documents." *Id.* at 4. According to the ALJ, "[o]n both January 9 and . . . 12, a representative of Mr. Sisco's office contacted a member of my staff, inquiring whether Respondents [could] submit documents by using electronic files; . . . on both occasions my staff member advised that only hard copies and facsimiles would be accepted." *Id.* The ALJ explained that on January 12, he directed his staff to return the flash drives which Respondents' counsel had sent to his office, and that as of the date of the hearing, Respondents still had not filed their proposed exhibits with his office. *Id.* at 4–5. The ALJ then explained that he had "considered the Government's report of the contents of what presumably was on" the flash drives, as well as Respondents' explanation as set forth in their Responses to the Government's Motions, and found that good cause existed to grant the motions and bar Respondents from introducing their proposed exhibits. *Id.* at 5. The ALJ, however, provided Respondents' counsel with the opportunity to submit its proposed exhibits as a proffer, provided it did so no later than February 10, 2015, and provided his Office with an original and two copies, as well as a copy to the Government. *Id.*

Subsequently, on February 3, 2015, the Government filed a "Notice of Objections to Respondent's Exhibits." ALJ Ex. 15 (Nos. 15–6 and 15–17). Therein, the Government noted that it had received eight binders of evidence totaling nearly 4,300 pages, of which five binders appeared to be related to Superior I and three binders Superior II. *Id.* at 2. While the Government contended that it was unclear whether the Respondents were offering the exhibits as a proffer or as evidence to be admitted in the proceeding, it then explained that even if the exhibits were offered as a proffer, they should not be included in the record because Respondent had not made an offer of proof as required by 21 CFR 1316.60. *Id.* The Government further noted that none of the documents were "self-authenticating" and many of them, which included patient medical records, "appear to come from sources other than the Respondents." *Id.* at 3.

At the first day of the evidentiary phase of the hearing, the ALJ addressed the Government's objection. Tr. 54. After re-affirming his earlier ruling which barred Respondents from introducing any documentary evidence, the ALJ then turned to the Government's contention that Respondents had not complied with 21 CFR 1316.60. On the issue of whether Respondents had made an adequate offer of proof, the ALJ asked one of Respondents' counsel if he was "correct in understanding that the Respondent[s'] Pre-hearing Statements and the premises that [he] articulated during the initial day of hearing in support of receiving these exhibits should, taken together, be regarded as containing the statement of the substance of the evidence which you would have accompany the excluded documents?" Tr. 58. Respondents' counsel answered "[y]es." *Id.* While the ALJ had also noted that "an offer of proof shall be part of the record only if a proper foundation has been laid for its admission," *id.* at 57, the ALJ did not ask Respondents' counsel to lay a foundation for any of the exhibits. *Id.* at 57–69. After noting that he received only a single copy of the proffered exhibits (vice the three copies required by his Prehearing Order), the ALJ ordered Respondents to provide two additional copies of the proffered exhibits prior to 5 p.m. that day; he further advised that if the copies were not filed, he would return the proffered exhibits to Respondents. *Id.* at 69. Subsequently, Respondents filed the additional copies of the exhibits, and the exhibits were forwarded as a proffer.

The ALJ's Ruling on Respondents' Subpoena Requests

During the January 27 hearing, the ALJ also addressed each Respondent's request for subpoenas. Tr. 17–23. As explained above, each Respondent submitted requests for an extensive number of subpoenas but failed to include with its requests a certificate of service establishing that they had provided copies to the Government.

Asked by the ALJ to address its requests, Respondents' counsel asserted that "the request for subpoenas was copied to [Government counsel] timely as to each of the subpoenas." *Id.* at 18. However, when asked by the ALJ if it was correct that he did not include a certificate of service, Respondents' counsel answered: "If the Court says that that wasn't included then I'll accept that. However, I will represent that everything that I provided to the Court has been provided to" Government counsel. *Id.* at 20. The ALJ then asked the Government's counsel if he had been provided with copies of the subpoena requests. *Id.* at 21. Government counsel answered that he had received a thumb drive which "contains so many thousands of pages of documents" that he "did not look for specific subpoenas." *Id.* Subsequently, Respondents' counsel confirmed that he had sent the subpoena requests to the Government electronically. *Id.* at 22.

The ALJ then explained that in his Prehearing Orders, he had advised the parties that subpoena requests that did not comply with his instructions would be returned without further action; he also explained that Respondents had neither objected to nor sought clarification of the Prehearing Orders. *Id.* at 23. Finding that Respondents had not complied with his Prehearing Orders, the ALJ announced that he would be returning Respondents' subpoena requests without further action. *Id.* The ALJ did not address whether Respondents had made an adequate showing as to relevancy with respect to either the patients or the physicians. *Id.* at 17–23.

Respondents' Motions for a Daubert Hearing and To Exclude the Testimony of the Government's Expert

On January 15, 2015, Respondents also filed motions to exclude the testimony of the Government's pharmacy expert Robert Parrado. ALJ Ex. 41 (No. 15–6); ALJ Ex. 41 (No. 15–7). The basis of Respondents' motions was that "Mr. Parrado's proposed opinions are based on nothing more than a cursory review of the written prescriptions to the exclusion of all other information," and that he "did not apply any reliable methodology as mandated" by *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny. ALJ Ex. 41, at 2 (No. 15–6); ALJ Ex. 41, at 2 (No. 15–7). Respondents also argued that Mr. Parrado was "not qualified to render any opinions regarding whether the physician issuing the prescriptions did so for a legitimate medical purpose in the usual course of professional practice." ALJ Ex. 41, at 2 (No. 15–6); ALJ Ex. 41, at 2 (No. 15–7) (both citing Fla. Stat. 766.102(5) ("person may not give expert testimony concerning the prevailing professional standard of care unless the person is a health care provider who holds an active and valid license and conducts a complete review of the pertinent medical records").

Respondents argued that the ALJ was required to perform a "gatekeeping" function in determining whether Mr. Parrado's testimony was admissible. ALJ Ex. 41, at 2 (No. 15–6); ALJ Ex. 41, at 2 (No. 15–7). They further argued that under *Daubert*, the Government was required to show that: (1) Mr. Parrado was qualified to testify as an expert; (2) that he used a sufficiently reliable methodology in reaching his conclusions; and (3) that his testimony would assist the trier of fact. ALJ Ex. 41, at 2 (No. 15–6); ALJ Ex. 41, at 2 (No. 15–7). Respondents then suggested that under *Daubert*, the ALJ was required to consider "whether the theory or technique" used by Mr. Parrado "has been subject to peer review and publication." ALJ Ex. 41, at 4 (No. 15–6); ALJ Ex. 41, at 4 (No. 15–7). According to Respondents, Mr. Parrado's testimony should be excluded as unreliable because "he failed to conduct a thorough investigation and failed to base his proposed opinion on any reliable methodology." ALJ Ex. 41, at 5(No. 15–6); ALJ Ex. 41, at 5 (No. 15–7).

The Government opposed the motions. Quoting agency precedent, the Government argued that where, as here, non-scientific expert testimony is at issue, the expert's " 'knowledge and experience' " may provide a sufficient foundation for concluding that his testimony is reliable. ALJ Ex. 50, at 3 (quoting *Holiday CVS, L.L.C., d/b/a CVS Pharmacy No. 219 and 5195*, 77 FR 63316, 62334 (2012) (quoting *Surles ex rel. Johnson* v. *Greyhound Lines, Inc.*, 474 F.3d 288, 295 (6th Cir. 2007))). The Government noted that Mr. Parrado has been a licensed pharmacist for more than 40 years and had been "the recipient of numerous professional appointments." *Id.* The Government further argued that at the hearing, Respondents would "have ample opportunity to question [him] regarding his knowledge and experience, but . . . to exclude him on that basis, prior to trial, is both misguided and premature." ALJ Ex. 50, at 4. The Government also argued that Respondents provided no support for their contention that Mr. Parrado's testimony should be excluded because "he did not interview [the] patients or other persons." ALJ Ex. 50, at 4.

The ALJ denied Respondents' motions. The ALJ reasoned that in each Show Cause Order and its Prehearing Statements, "the Government identifie[d] red flags or other conditions which, according to the Government, triggered a corresponding obligation on the part of pharmacies who were presented with a number of prescriptions. The thrust of this evidence is [not] dependent upon scientific or technical analysis, but upon documentary or testimonial evidence establishing or rebutting the claimed corresponding obligation." ALJ Ex. 7, at 7 (Nos. 15–6 and 15–7).

The ALJ then held that "[t]he Government ha[d] made a sufficient showing to permit Mr. Parrado to appear and give testimony." *Id.* Continuing, the ALJ explained that at the hearing, he would allow Respondents to question Mr. Parrado as to his qualifications and the methodology he used, but that he was not making a "preclusive ruling prior to the time [he] testified." *Id.* The ALJ thus denied Respondents' motions to either conduct a separate hearing on the admissibility of Mr. Parrado's testimony or to exclude his testimony prior to the hearing. *Id.*

Respondents' Motions for a Continuance

On January 15, 2015, each Respondent also moved for a continuance. ALJ Ex. 42 (No. 15–6); ALJ Ex. 42 (No. 15–7). Respondents sought a continuance of the proceeding "to commence no sooner than June 2015." *See, e.g.*, ALJ Ex. 42, at 5 (No. 15–6). Respondents asserted that they needed the continuance "to interview and subpoena witnesses," and that they "ha[d] timely requested the issuance of numerous subpoenas and . . . ha[d] exercised due diligence in this regard." *Id.* at 3. Respondents further asserted that "[d]ue to the short time period between the issuance of the order[s] to show cause and the commencement of the hearing, and the numerous potential witnesses, [they] will undoubtedly be prejudiced by a [sic] the lack of time to adequately interview and obtain service on the necessary witnesses." *Id.*

Respondents argued that "the Government has had years to prepare its case whereas [they have] only been afforded a few months." *Id.* at 4. Continuing, Respondents contended that the Government "has had more than 20 months to process and analyze the seized information," and that "[d]uring this time, the information was not available to Respondent." *Id.* at 5. While Respondents then acknowledged that "a portion of the seized information, most notably the prescriptions, was provided to [them] in electronic format," they then contended that "the sheer volume of information coupled with the unreasonably short deadlines surrounding the holiday season makes analysis of the information . . . impossible." *Id.*

On January 27, 2015 (during the initial day of the hearing), the ALJ denied Respondents' motions.[10] In so ruling, the ALJ relied on his previous ruling that Respondents had "failed to timely submit their request for subpoenas." Tr. 30. The ALJ then explained that he could not "reconcile" Respondents' assertion that they needed more time to prepare with the representations made in each of their Prehearing Statements that their two proposed experts had "reviewed the prescriptions at issue, the relevant inventory and ordering history and prepared summaries of the pharmacies' dispensing activities during 2011 and 2012." Tr. 31; *see also* ALJ Ex. 9, at 5–6 (No. 15–6); ALJ Ex. 12, at 5–6 (No. 15–7).[11] Finally, the ALJ explained that he had:

> consider[ed] a variety of factors, including the diligence and good faith of the parties seeking the continuance; the grounds for the delay; fairness to both parties; the need for orderly administration of justice; the length

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[10] The Government did not file a response to this motion.

[11] As found above, in their Prehearing Statements, Respondents represented that Mr. Badawi would testify about "the procedures used at Superior Pharmacy [I and II] to consider and resolve alleged 'red flags,' inventory, ordering and CSOS compliance issues. Mr. Badawi will further testify that he has reviewed the prescriptions at issue, the relevant inventory and ordering records and prepared summaries of the prescription dispensing activity at Superior Pharmacy [I and II] during 2011 and 2012, and identified significant errors in the inventory performed by the DEA." ALJ Ex. 9, at 6 (No. 15–6); ALJ Ex. 12, at 6 (No. 15–7).

Likewise, Respondents represented that "Mr. Crowley will testify regarding errors in the audits performed by the agent/investigators of Superior Pharmacy [I and II]. Mr. Crowley reviewed the prescriptions, inventory and CSOS records of Superior Pharmacy [I and II]. Mr. Crowley will further testify regarding Superior Pharmacy[I and II]'s procedure for resolving potential 'red flag' issues and compliance with recordkeeping requirements related to inventory records, DEA–222 order forms and CSOS issues." ALJ Ex. 9, at 5 (No. 15–6); ALJ Ex. 12, at 5 (No. 15–7).

> of the delay requested; whether other continuances have been requested and received; the inconvenience to litigants, witnesses, opposing counsel and the Court; and whether the requesting party contributed to the circumstances which give rise to the request for a continuance and any other relevant factors depending on the facts of the case.

Tr. 31. The ALJ then found that "cause has not been shown to delay this hearing" and denied the Respondents' motions. *Id.*

With the evidentiary phase of the hearing set to begin on February 10, 2015, on February 6, 2015, Respondents filed a second Motion for Continuance. ALJ Ex. 12, at 1 (No. 15–6/15–7). The basis for the motion was that on January 28, 2015, they had retained a third counsel, who previously been involved in resolving a matter involving another of Mr. Obi's pharmacies. *Id.* at 2. Citing "the complexity of the issues in these matters," Respondents sought a continuance of three weeks to allow its additional counsel to prepare for the hearing. *Id.*

The same day, the Government objected. ALJ Ex. 19 (Nos. 15–6/15–7). It argued that Respondents had been aware of the allegations since October 16 and 17, 2014, and that "neither Respondent has been without counsel since" they were served with the Show Cause Orders, and that Superior I had previously retained an additional counsel. *Id.* at 3. The Government further asserted that it was "both disingenuous and . . . legal gamesmanship to suggest that the eleventh hour appearance of a co-counsel for Superior II and a second co-counsel for Superior I constitute grounds for disrupting a proceeding that" in its view had commenced on January 27, 2015. *Id.* It then argued that Respondents had not demonstrated any hardship that justified a continuance and they "ha[d] never *timely* objected to any" of the dates set by the ALJ, "including the date and location of the hearing which" had been set "more than two months" earlier. *Id.* at 4. Finally, the Government stated that it was prepared to put on its case and that "all of [its] witnesses are travelling to Arlington, Virginia, and have set aside time to participate in this matter." *Id.* The Government thus argued that "any further delay" would cause it prejudice. *Id.*

The ALJ denied Respondents' motion. ALJ Ex. 24, at 2 (Nos. 15–6/15–7). As with Respondents' previous motions for a continuance, the ALJ explained that he had considered various factors and found that "cause has not been shown to delay the hearing." *Id.*

The Evidentiary Hearing and ALJ Decision

On February 10 and 11, the ALJ conducted the evidentiary phase of the hearing at the DEA Hearing Facility in Arlington, Virginia. At the hearing, the Government elicited the testimony of four witnesses, including its expert witness, Mr. Robert Parrado; the Government also introduced various documents into evidence. Consistent with the ALJ's order granting the Government's Motions *in Limine,* Respondents were precluded from calling any witnesses and introducing any documentary evidence. The ALJ did, however, allow Respondent to submit ten binders of documents (totaling nearly 4,300 pages) as a proffer.

Following the hearing, both parties submitted briefs containing proposed findings of fact and conclusions of law (hereinafter, referred to as Post-Hearing Brief). On April 9, 2015, the ALJ issued his Recommended Decision (hereinafter, cited as R.D.); according to the Certificate of Service, on April 10, the ALJ's law clerk sent a copy of the Decision to all three of Respondents' counsels by Federal Express.

In the Recommended Decision, the ALJ relied on the Government's evidence with respect to factors two and four to conclude that "the Government has established its *prima facie* case by at least a preponderance of the evidence that Respondents' continued . . . registrations would be inconsistent with the public interest." R.D. 87. Further finding that "Respondents have failed to rebut that case through a demonstration of sufficient remediation," the ALJ recommended that I revoke each Respondent's registration and deny any pending applications to renew or modify its registration. *Id.*

On May 4, 2015, the ALJ transmitted the record to my Office. On May 6, 2015, Respondents filed a brief captioned as: Exceptions to the Recommended Decision and Request for Removal of the ALJ (hereinafter, cited as Resp.' Exceptions). Respondents, however, offered no showing of good cause to excuse the untimely filing of their brief. *See generally id.* In response, on May 7, 2015, the Government filed with my Office a motion to strike Respondents' Exceptions as untimely or, in the alternative, to respond to their Exceptions. *See* Gov. Motion to Supplement the Record, Strike Respondent[s'] Untimely Filed Exceptions to the Recommended Decision of the Administrative Law Judge Or, In the Alternative, Respond to Exceptions. Because Respondents have not demonstrated good cause to excuse the untimely filing of their Exceptions, I consider the claims raised therein only if they were previously raised in their Post-Hearing Brief.

Having carefully considered the entire record in this matter and, in particular, the claims of error raised by Respondents in their Post-hearing Brief, I do not adopt the ALJ's findings of fact and conclusions of law with respect to the allegations that each Respondent's pharmacists violated 21 CFR 1306.04(a) and 1306.05(a). I do, however, adopt the ALJ's findings of fact and legal conclusions with respect to: (1) The allegations pertaining to the audits conducted of each pharmacy, (2) the allegations that Respondents were not properly maintaining required records including their schedule II order forms, and (3) that for purchases made using the electronic Controlled Substance Order System, Superior II was not electronically linking its receipt records to its purchase records. I further find that Respondent Superior II violated DEA regulations by allowing a non-authorized person to place electronic orders using the key assigned to an authorized person. I therefore conclude that the Government has made out a *prima facie* case to support revocation of Respondents' registrations. And because Respondents have produced no evidence of any corrective measures they have undertaken, I will order that their registrations be revoked and that any pending applications be denied. As ultimate fact finder, I make the following.

Findings of Fact

The parties stipulated that Respondent Superior I holds DEA Certificate of Registration BS9255274, pursuant to which it is authorized to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered address of 3007 W. Cypress St., Suite 1, Tampa, Florida. ALJ Ex. 7, at 2 (Nos. 15–6/15–7).

The parties stipulated that Respondent Superior II holds DEA Certificate of Registration BS9699731, pursuant to which it is authorized to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered address of 5416 Town 'N' Country Blvd., Tampa, Florida. *Id.*

The DEA Investigation

On February 4, 2013, DEA Investigators executed Administrative Inspection Warrants at Respondents Superior I and Superior II. Tr. 370–71; 471. With respect to Superior I, the Investigators seized the original prescriptions for its schedule II and III dispensings, as well as its schedule II order forms (DEA-Form 222), invoices, and inventory records. *Id.* at 372. At Superior I, a DEA Investigator (who assisted the lead Investigator) also conducted an inventory of the controlled substances then on hand with the assistance of the pharmacist on duty, who verified the count; the Investigator also obtained a copy of an inventory taken by Superior I which was dated May 2, 2011. *Id.* at 373–78. According to a DI, because the May 2, 2011 inventory "did not include all the drugs that were a part of the audit," he asked the lead Investigator to contact the pharmacy for additional inventory records, and on February 11, 2013, Superior I provided additional records which included a "bi-annual inventory" and an "in-house inventory." *Id.* at 378–79.

Likewise, with respect to Superior II, the lead Investigator on the warrant testified that she seized the original schedule II prescriptions and the pharmacy's purchasing records for the drugs that were subject of the audit; the DI also testified she obtained the pharmacy's schedule II order forms as well as a perpetual inventory maintained by the pharmacy which was dated July 31, 2012. *Id.* at 472, 474, 477. The DI also took an inventory of the controlled substances then on hand, with the DI witnessing Superior II's pharmacist counting of the pills. *Id.* at 477.

As part of the investigations, the Government provided various schedule II prescriptions which were dispensed by each pharmacy to its expert Mr. Robert Parrado, who reviewed them to determine if they were dispensed in compliance with the Controlled Substances Act. Mr. Parrado testified that he obtained his B.S. in Pharmacy in 1970 from the University of Florida College of Pharmacy and that he has held a Florida pharmacist's license since 1971. Tr. 122; GX 2, at 1 (No. 15–6/15–7). Mr. Parrado testified that he has practiced as a pharmacist at both community pharmacies as well as hospital pharmacies; he also testified that he had been the Pharmacy Department Manager at multiple pharmacies, including two pharmacies that he owned for approximately 19 years. Tr. 124–26; GX 2, at 1–2.

Mr. Parrado was a member of the Florida Board of Pharmacy from January 2001 through February 2009, and had served as both Vice Chairman and Chairman of the Board. Tr. 128–29; GX 2, at 3. He is a member of the Florida Pharmacy Association, having served as both its President and then Chairman of the Board. GX 2, at 3. He is also a member of the Hillsborough County Alcohol & Drug Abuse Task Force, the National Community Pharmacists Association, and the American Society for Pharmacy Law. *Id.* Finally, he has made numerous presentations on the dispensing of controlled substances by pharmacists, *id.* at 3–7, and has testified as an expert witness for both the prosecution and defense in criminal and administrative matters. Tr. 133; *see also id.* at 152 (answering "no" when asked on *voir dire* if, in criminal matters, he has always testified for the Government).

Asked to explain what the standard of care (in Florida) requires of a pharmacist who is presented with a prescription for a controlled substance, Mr. Parrado testified:

> You have to ensure that the prescription is appropriate and that it's valid. And in doing that he has to look at the prescription. He has to understand the nature of the drug, the nature of the disease state that they're treating, the appropriateness of the therapy and the dosing.
>
> And then make sure that the prescription was issued under . . . the valid circumstances of a physician . . . having written the prescription in the course of his practice and that the prescription is . . . for [a] legitimate medical purpose.

Id. at 137.

Asked to explain what a "red flag" is as it relates to the dispensing of controlled substances, Mr. Parrado then testified that:

> [a] red flag is anything that will cause the pharmacist concern as to the validity of that prescription. It could be numerous things.
>
> And a lot of times it's just dependent on the patient presenting the prescriptions or the circumstances. Or just looking at the prescription itself might raise a red flag . . . and cause you concern.

Id. at 138.

Mr. Parrado then proceeded to identify various red flags, including if the prescription was for "a known drug of abuse" and if the dosing is "appropriate."[12] *Id.* Continuing, Mr. Parrado explained that after "mak[ing] sure the dosing is appropriate . . . you look at the quantity of tablets" and ask if it is "an appropriate therapy for the condition . . . [t]hat the physician is treating." *Id.* at 139. Mr. Parrado then testified that he looks at what he termed the "triangle"—the locations of "the patient['s] home, the physician's office and the pharmacy" and that "whenever one of those legs seems to get a little bit long I seem to get a little concerned," thus leading him to "want to verify why a person would drive a long way to [go] to a particular clinic" and why the person would "drive a long way from that clinic to a pharmacy." *Id.* at 140.

Mr. Parrado also identified other red flags to include "[m]ultiple people presenting with identical or very similar prescriptions from the same clinic," as well as where a person presents prescriptions for "cocktails that are known to be abused on the street." *Id.* Mr. Parrado then explained that a cocktail "is a combination of drugs," which usually includes an "opioid such as oxycodone or hydromorphone," "a benzodiazepine such as Xanax or Valium," and "a muscle relaxant such as Soma." *Id.* at 140–41.

Mr. Parrado further identified as a red flag the circumstance where multiple persons present the "same prescriptions" from either "the same practitioner" or "clinic." *Id.* at 141. Mr. Parrado then explained that multiple persons getting the same prescriptions "from the same clinic" would be a red flag because "there's supposed to be an individualization of therapy whenever a physician is ordering a pain medication."[13] *Id.* Of similar import, Mr. Parrado testified that he was familiar with the term "pattern prescribing," which he explained was when "prescriptions com[e] from the same clinic in . . . the same drug," with the same or "very similar" dosing and quantities. *Id.* at 142. Reaffirming his earlier testimony, Mr. Parrado explained while "there could be a small difference" in the quantity (*i.e.*, 168 vs. 180 pills) prescribed, "[t]hat doesn't show me that there's any attempt at individualization of therapy." *Id.*

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[12] At this point, Respondents' counsel objected on the ground that the testimony was "outside the scope of the" Government's Prehearing Statements. Tr. 138. However, in its Prehearing Statements, the Government notified Respondents that Mr. Parrado would identify and discuss "prescriptions for controlled substances which are known to be highly abused" and "prescriptions for quantities of narcotics that exceeded the recommended daily dosages." ALJ Ex. 6, at 3 (No. 15–6); ALJ Ex. 7, at 3 (No. 15–7). I thus find that the ALJ properly overruled the objection.

[13] Here again, Respondents objected to the testimony, asserting that it was "outside the scope of [Mr. Parrado's] testimony" and that Mr. Parrado was not "qualified to testify about what the standard of care is for . . . a healthcare practitioner" under Florida Statute § 766.102. Tr. 141–42. Of note, in its Prehearing Statements, the Government disclosed to Respondents that Mr. Parrado would discuss "prescriptions issued to multiple individuals presenting prescriptions for the same drugs in the same quantities from the same doctor." ALJ Ex. 6, at 3 (No. 15–6); ALJ Ex. 7, at 3 (No. 15–7). The ALJ overruled the objection. Tr. 142. Respondent did not, however, explain how it was prejudiced because the Government then asked whether a red flag was also presented because the prescriptions came from the same clinic. As for Respondent's contention that Mr. Parrado was not qualified under the Florida Statute to render an opinion on the issue, Florida law does not control the scope of permissible testimony in this proceeding.

Mr. Parrado then identified two more red flags. The first of these is when "two people in the same household or [with the] same address were needing the exact same drugs." *Id.* at 143. While Mr. Parrado explained that this could possibly be legitimate, the "onus of verifying that prescription has been seriously moved up a notch." *Id.* Mr. Parrado then testified that a red flag is also raised when prescriptions are issued to multiple persons with the same last name. *Id.*

Asked by the Government what steps a pharmacist should take upon being presented with a prescription that raises a red flag, Mr. Parrado explained:

> At that point the pharmacist—first thing he has to do, he has to verify that prescription with the prescriber. Florida law says you check with the prescriber.
>
> Not the prescriber's office, with the prescriber. And then you speak with the prescriber and get his opinion.
>
> You ask him the questions that you feel, you know, address your concerns. And then at that point I have to . . . use my professional judgment. Did I believe him or not.
>
> Because a physician who had written a script is always going to say, yes they wrote it. But I'm trying to determine if it was written for a legitimate medical purpose. So that's why I'm asking the questions I'm asking.

Id. at 144.

Continuing, the Government asked Mr. Parrado if some red flags are unresolvable, prompting objections by each Respondent that this testimony was beyond the scope of the summary of the testimony disclosed by the Government in its Prehearing Statements. *Id.* at 144–45. The ALJ overruled the objections [14] and Mr. Parrado testified:

> Well anytime that there is a red flag my job is to resolve that red flag. And at that point I'm having to use my professional judgment when I'm weighing all the different factors that are causing me concern.
>
> If I cannot resolve all these things that are bothering me, at that point that becomes unresolvable and I cannot fill that prescription.

Id. at 145–46. *See also id.* at 361 (agreeing that a pharmacist's education, experience and training inform his/her professional judgment).

The Government then asked Mr. Parrado if a retail pharmacist would document his/her resolution of a red flag "somewhere?" *Id.* at 146. Mr. Parrado answered: "Absolutely. Anytime you have a concern with appropriateness of therapy, you always do what you have to do to resolve it and then you document it on the prescription." *Id.* Asked by the Government if the resolution of a red flag "would be documented on the prescription itself," Mr. Parrado answered: "Yes. Unless you have another form of doing that I don't know about, but the standard of practice has always been you document it on the prescription." *Id.*

On Respondent's *voir dire*, Mr. Parrado was asked whether "the manner in which a pharmacist documents their [sic] efforts to resolve red flags is not mandated by any statute, regulations or guidance document?" *Id.* at 154. Mr. Parrado answered: "The pharmacist has a duty to verify that's done. And when he's done that he needs to document it. Because if you haven't documented it you haven't done it." *Id.* Upon further questioning by Respondents, Mr. Parrado acknowledged that neither the Florida Statutes nor the Florida Administrative Code state where the pharmacist has to document his/her resolution of a red flag. *Id.* at 156.

On further *voir dire* by Respondents, Mr. Parrado testified that his opinions were not based on conversations he had with the pharmacists at Respondents, or any statements of the pharmacists provided to him by DEA. *Id.* at 158. He also testified that his opinions were not based on any statements made by the patients, or the prescribers. *Id.* at 158–

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[14] This was the first of several objections to the Government's elicitation of testimony from its Expert as to whether some of prescriptions presented red flags that could not be resolved. As Respondents argued, the Government Pre-hearing Statements "do [ ] not anywhere discuss irresolvable red flags. And this is a last minute attempt to prejudice the ability of the Respondent[s] to put on a case here." Tr. 144.

One of the fundamental tenets of Due Process is that the Agency must provide a respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action. *See NLRB* v. *I.W.G., Inc.,* 144 F.3d 685, 688–89 (10th Cir. 1998); *Pergament United Sales, Inc., v. NLRB,* 920 F.2d 130, 134 (2d Cir. 1990). *See also* 5 U.S.C. 554(b) ("Persons entitled to notice of an agency hearing shall be timely informed of . . . the matters of fact and law asserted.").

However, " '[p]leadings in administrative proceedings are not judged by the standards applied to an indictment at common law.' " *Citizens State Bank of Marshfield* v. *FDIC,* 751 F.2d 209, 213 (8th Cir. 1984) (quoting *Aloha Airlines* v. *Civil Aeronautics Bd.,* 598 F.2d 250, 262 (D.C. Cir. 1979)). *See also Boston Carrier, Inc.* v. *ICC,* 746 F.2d 1555, 1560 (D.C. Cir. 1984) (quoted in *Edmund Chein,* 72 FR 6580, 6592 n.21 (2007) ("an agency is not required 'to give every [Respondent] a complete bill of particulars as to every allegation that [he] will confront"). Thus, the failure of the Government to disclose an allegation in the Order to Show Cause is not dispositive, and an issue can be litigated if the Government otherwise timely notifies a respondent of its intent to litigate the issue.

The Agency has thus recognized that "the parameters of the hearing are determined by the prehearing statements." *Darrell Risner, D.M.D.,* 61 FR 728, 730 (1996). Accordingly, in *Risner,* the Agency held that where the Government has failed to disclose "in its prehearing statements or indicate at any time prior to the hearing" that an issue will be litigated, the issue cannot be the basis for a sanction. 61 FR at 730. *See also Nicholas A. Sychak, d/b/a Medicap Pharmacy,* 65 FR 75959, 75961 (2000) (noting that the function of prehearing statements is to provide Due Process through "adequate . . . disclosure of the issues and evidence to be submitted in . . . proceedings"); *cf. John Stafford Noell,* 59 FR 47359, 47361 (1994) (holding that notice was adequate where allegations were not included in the Order to Show Cause but "were set forth in the Government's Prehearing Statement").

However, consistent with numerous court decisions, the Agency has also held that even where an allegation was not raised in either the show cause order or the prehearing statements, the parties may nonetheless litigate an issue by consent. *Pergament United Sales,* 920 F.2d at 135–37; *see also Duane* v. *Department of Defense,* 275 F.3d 988, 995 (10th Cir. 2002) (discussing *Facet Enterprises, Inc., v. NLRB,* 907 F.2d 963, 974 (10th Cir. 1990); "we held that defendant had constructive notice of an alternate theory of liability not described in the formal charge when the agency detailed that theory during its opening argument and at other points during the hearing and when the defendant's conduct revealed that it understood and attempted to defend against that theory"). *See also Grider Drug #1 & Grider Drug #2,* 77 FR 44070, 44077 n.23 (2012) (holding that while the Government did not provide adequate notice of its intent to litigate an allegation in either the show cause order or its prehearing statements, where respondents "did not object that the allegation was beyond the scope of the proceeding and that they were denied adequate notice of it" and "fully litigated the issue," the allegation was litigated by consent) (citing *Citizens State Bank,* 751 F.2d at 213; *Kuhn* v. *Civil Aeronautics Bd.,* 183 F.2d 839, 841–42 (D.C. Cir. 1950); and *Yellow Freight System, Inc.,* v. *Martin,* 954 F.2d 353, 358 (6th Cir. 1992)).

Here, I conclude that the ALJ erred when he overruled Respondents' objections to the testimony, as neither the Show Cause Orders, nor the Government's Prehearing Statements ever identified any prescription as presenting red flags that could not be resolved. As the Second Circuit has explained, "[t]he primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the complaint and fashioning an explanation that refutes the charge of unlawful behavior." *Pergament United Sales,* 920 F.2d at 135 (citation omitted). The defense of the allegation that a prescription presented red flags that could not be resolved requires entirely different proof, *i.e.,* testimony as to why a prescription did not lack a legitimate medical purpose, than the defense of the allegation that a pharmacist failed to resolve red flags, and Respondents' multiple objections make clear that they did not consent to the litigation of the issue. Accordingly, the Expert's testimony to this effect cannot be considered in determining whether Respondents' pharmacists violated their corresponding responsibility under 21 CFR 1306.4(a).

59.[15] Over Respondents' objections,[16] Mr. Parrado was accepted as an expert. *Id.* at 165.

Mr. Parrado then testified that he was retained to "review the prescriptions." *Id.* at 166. He also acknowledged having "reviewed some patient records" and "a patient profile," before clarifying that "the main thing [he] relied on was the prescriptions and those partial patient records."[17] *Id.*

The Superior I Prescriptions

The Government then proceeded to question Mr. Parrado regarding the 25 prescriptions contained in Government Exhibit 3 (No. 15–6). *Id.* at 167. Each of the prescriptions was issued by a physician at the 24th Century Medical Center, which, according to the prescriptions, was located at 7747 W. Hillsborough Avenue in Tampa. GX 3. Sixteen of the prescriptions were issued on August 5, 2011 for oxycodone 30 and were filled by Superior I on the same day. *See id.* at 1–16; Tr. 169. Moreover, 13 of these 16 prescriptions were written by the same physician (Dr. C.), with the remaining three written by another physician (Dr. R.). GX 3, at 1–16.

Each page of this exhibit contains two images; one showing the front of the prescriptions; the other showing the back. *See generally* GX 3. With respect to the first page of the exhibit, Mr. Parrado testified that the bottom image was the back of the prescription. Tr. 169. He explained that when a pharmacy fills a prescription, its computer generates labels, one of which goes on the prescription bottle and the other goes on the prescription. *Id.* Mr. Parrado then explained that the number following the letters "RX" on the label was the prescription number and that the number is generated sequentially by the pharmacy's "computer as prescriptions are being filled." *Id.* at 170–71. However, Mr. Parrado subsequently testified that "[d]epending on the computer format they have, some will generate a number with the first number being different . . . depending on the schedule of the drug." *Id.* at 174.

The Government then asked Mr. Parrado whether there were "any red flags associated with" the 16 prescriptions, which were filled on August 5, 2011. *Id.* at 178. Mr. Parrado testified that the prescriptions presented multiple red flags:

> Well first thing I would see was the drug, [o]xycodone, 30 milligrams. Then I would see that they're all coming from the same clinic. They're all for the same strength written by the same physician on the same day.
>
> So there's multiple patients coming from the same clinic. Which was one of my concerns earlier. Multiple people presenting from the same clinic with a like or similar prescription.
>
> These are definitely alike in similar prescriptions. So that would be my first red flag.
>
> Then the next red flag I would have looked at was the dosing. The appropriateness of therapy. A red flag I would have to resolve at this point was knowing that 80 milligrams a day of [o]xycodone is a lethal dose to an opioid naïve patient. These are much higher than 80 milligrams a day dosing.
>
> I would have to verify—I'd have to feel good about the fact that the patient had been on this drug therapy and established to this dose. Would have been the first thing.
>
> Then the next thing I would have looked at would have been the patient[']s address. How far he drove to get there.
>
> Then another thing I would have looked at was what . . . did he pay for it with cash. And how much did he pay. How much is he willing to pay for.[18]

Id. at 178–79.

Mr. Parrado further testified that each of the 16 prescriptions was paid for in cash. *Id.* at 181. Asked whether based on his experience and knowledge of retail pharmacy practice, the prices being charged by Respondent for these prescriptions "were considered high prices for oxycodone," Mr. Parrado answered "[v]ery." *Id.* at 182. Mr. Parrado subsequently explained that "these prices are very, very high" and that this would be an additional red flag. *Id.*at 183. As the evidence shows, 13 of the patients paid $784 or more for their prescriptions, and five of the patients paid $952 or more. GX 3, at 1–16.

The Government then questioned Mr. Parrado regarding the red flags presented by the relative location of the patients to the prescriber and Superior I. With respect to the prescriptions reproduced at pages one (112 oxycodone 30 to M.L.) and nine (224 oxycodone 30 to V.P.), both patients' addresses were listed as being in Spring Hill, Florida.[19] *See id.* at 1, 9. According to Mr. Parrado, Spring Hill is located 45 to 50 miles from Superior I.[20] Tr. 185. Mr. Parrado then explained that "[t]here are many pharmacies between Spring Hill and Tampa." *Id.*

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[15] Regarding whether his opinions were based on the presentations on red flags made by the former head of the Agency's Office of Diversion Control, Mr. Parrado acknowledged that he has seen these presentations on two occasions. Tr. 159. However, Mr. Parrado stated that the presentations "reinforced" his existing opinions on red flags. *Id.* at 160. As for the presentations he had previously given, Mr. Parrado acknowledged that he no longer considers a patient's asking for a drug by brand name to be a red flag. *Id.* at 161–62.

When asked whether his opinions were based on information in the DEA *Pharmacist's Manual,* Mr. Parrado answered "yes", and when asked if he disagreed with anything in the *Manual* as it relates to red flags and their resolution, answered "no." *Id.* at 163.

[16] The basis of Respondents' objection to Mr. Parrado being accepted as an expert was that he "is a practicing pharmacist. He's experienced in retail pharmacy but qualification as an expert, there's no need." Tr. 165. Given Mr. Parrado's extensive years of practice as a retail pharmacist; his years as a member of the Florida Board of Pharmacy, which includes service as both Vice Chairman and Chairman; his involvement in the Florida Pharmacy Association which includes his service in leadership positions; his membership in other professional associations; and his numerous presentations; the ALJ properly overruled Respondents' objection.

[17] On cross-examination, Mr. Parrado testified that he had review only one patient profile "a couple of weeks" before the hearing. Tr. 232.

[18] At this point, Mr. Parrado testified that "in that time period," oxycodone cost from $.33 to $1.00 per tablet, at which point Respondents' counsel objected to the testimony, asserting that it was outside the scope of the Government's Prehearing Statements and that there was no foundation for Mr. Parrado's testimony. Tr. 179. While the Government's Prehearing Statement did not disclose the precise prices he testified to, the Government did disclose that Mr. Parrado would "identify and discuss . . . prescriptions for individuals playing [sic] high prices . . . for controlled substances with cash." ALJ Ex. 6, at 3 (No. 15–6). Moreover, the label attached to the back of each of the prescriptions contains data as to both the price to the patient and the cost of the prescription and the prescriptions were provided to Respondents prior to the hearing. The labels suggest that Mr. Parrado's testimony as to the cost per tablet was accurate. *See, e.g., generally* GX 3 (No. 15–6).

As to the issue of foundation, Mr. Parrado testified that "I know the pharmacy I was working in at that time [was] paying about $.33 a pill for [o]xycodone." Tr. 182. He then added that the average price charged to a patient "may have gotten to a $1.00." *Id.* On cross-examination, Mr. Parrado further testified that his knowledge of pricing was not based on his having called individual pharmacies, but rather his "general knowledge of what the market place was." Tr. 242.

[19] *See also* GX 3, at 2 (Rx for 160 oxycodone 30 to J.R.).

[20] Here again, Respondents objected to Mr. Parrado's testimony, arguing that the Government's Prehearing Statement did not disclose that he was "going to be offering testimony with regard to the distances between locations or the relative locations of these patients and the pharmacy." Tr. 184. Respondents further argued that they had "prepared to cross examine the person who [the Government] said would testify to that. It was the intelligence analyst. It is not Mr. Parrado." *Id.*

It is correct that the Government did not disclose in its Prehearing Statement for Superior I that Mr. Parrado would specifically testify about the distances between Superior I and the towns of Spring Hill (as well as New Port Richey and others). It also true that in its Prehearing Statement, the Government indicated that it intended to call a different witness (an intelligence analyst) to testify about a chart she created showing the large number of Superior I's patients who lived long distances from the pharmacy. However, the Government also disclosed that it intended to ask the ALJ to take official notice of the approximate mileage between Superior I and the various municipalities where the patients lived. Moreover, the distances between Superior I and the towns of Spring Hill and New Port Richey are disputable only to the extent one argues over the precise addresses used to ascertain that distance or the route taken. I thus conclude that Respondent cannot show how it was prejudiced by the ALJ's overruling of its objection.

Regarding the prescriptions reproduced at page four (168 oxycodone 30 S.M.) and 16 (224 oxycodone 30 for S.A.), Mr. Parrado testified that both patients gave addresses in New Port Richey. *Id.* He then testified that New Port Richey is "[a]bout 40 miles north of Tampa." *Id.* Mr. Parrado then noted that patient addresses for other prescriptions included Bradenton (40–45 miles south and west of Tampa), *id.* at 186; Port Richey (which is next to New Port Richey), *id.* at 187; Ocala (90–100 miles north of Tampa), *id.* at 188; Gainesville (130 miles north of Tampa), *id.;* High Springs ("probably a 150 miles" from Tampa), *id.* at 188–89; Jacksonville (200 miles north and east of Tampa), *id.* at 189–90; Alachua (140–150 miles from Tampa); *id.* at 190; Middleburg ("[c]lose to Jacksonville" and "about 200 miles" from Tampa); *id.* at 191; and Uvalda, Georgia ("probably . . . close to 300 miles" from Tampa). *Id.* at 192.

Next, the Mr. Parrado testified that each of the 16 prescriptions was "facially invalid" because the prescribing physician did not include the patient's address. *Id.* Mr. Parrado explained that under Florida law "at the time[21] . . . the patient name and address had to be on the front of the prescription." *Id.* While Mr. Parrado testified that a missing address is a red flag, he acknowledged that the pharmacist could resolve it by adding in the patient's address. *Id.* Asked by the Government whether it appeared that Superior I's pharmacists had resolved this red flag with respect to the prescriptions reproduced at pages one and four of GX 3, Mr. Parrado acknowledged that it appeared that they had done so as evidenced by the "computer generated sticker[s] that the pharmacist[s] put" on the prescriptions. *Id.* at 193. However, Mr. Parrado then explained that it "would have been [the pharmacist's] duty" to verify that the address on the sticker "was accurate." *Id.*

The Government then asked Mr. Parrado about the prescriptions found at pages 11 (RX#452161), 12 (RX#452160), 14 (RX#452156), 15 (RX#452155), and 16 (RX#452159). Tr. 194–95. Of note, these prescriptions were issued to patients who reported their addresses respectively as being in High Springs, Alachua, Middleburg, Florida; Uvalda, Georgia; and New Port Richey, Florida. *See* GX 3, at 11–12, 14–16. Specifically, the Government asked whether "the fact that these numbers are so close together, looking at these prescriptions collectively, does that raise any additional red flags for you?" Tr. 195. After the ALJ overruled Respondent's objection that the testimony was outside the scope of the Prehearing Statement, Mr. Parrado answered:

> Yes. Yes, it would have caught my attention that we had people coming from long distances and places that were close together, coming to get these prescriptions.
>
> What I don't see on there is, you know, it looks like the [patient address] sticker was put on the front to resolve the red flag. It doesn't tell me how they resolved the red flag.

Id.

The Government then asked Mr. Parrado about the prescriptions reproduced at pages 13 (RX#452157) and 14 (RX#452156); these prescriptions listed the patient's addresses as being in Jacksonville (J.M.) and Middleburg, Florida (B.M.). *Id.* at 196; GX 3, at 13–14. According to Mr. Parrado, these "two prescriptions were filled sequentially for people from Middleburg and Jacksonville, which are both very close to each other." Tr. 196. Continuing, Mr. Parrado opined: "So they could have travelled together to come there."[22] *Id.* Mr. Parrado further observed that these patients had the same last name. *Id.* at 197.

Next, the Government asked Mr. Parrado about the prescriptions reproduced at pages 14 and 15. Of note, the latter prescription was issued to a patient (C.M.), who provided an address in Uvalda, Georgia and who has the same last name as that of the patients discussed in the preceding paragraph. *See* GX 3, at 15. Mr. Parrado again opined that he believed these persons travelled together to obtain the prescriptions. Tr. 198. Asked by the Government—over the overruled objection of Respondent—whether the red flags presented by these were resolvable, Mr. Parrado explained:

> These are the kinds of prescriptions that would cause me not to be able to resolve that—this many red flags together. The long distance, the same name, the like, similar drugs, thousands of dollars involved here, in cash, would cause me . . . concern.
>
> It's not, in my practice, it's not been—the average customer doesn't come into the pharmacy with $1,000 in their pocket. You know, it's average you tell the person they have a $20 copay they get upset.
>
> For these process [sic] to be charged, you know, it's just—that's a red flag that I would have a hard time resolving.[23]

Id. at 199. Asked the same question with respect to the prescriptions reproduced at pages 13 and 14, Mr. Parrado testified: "It would be the same answer. It's the same situation."[24] *Id.* at 200.

The Government then asked Mr. Parrado whether, with respect to the 16 oxycodone 30 prescriptions (GX 3, at 1–16), which were issued and filled on August 5, 2011, there was any evidence, other than the placement of the address stickers, that the red flags they presented "were resolved?" Tr. 200. Mr. Parrado testified: "[t]here is no documentation to that effect on any of these prescriptions." *Id.* Following up, the Government asked Mr. Parrado if he had seen any evidence "that any of the red flags [other than the missing addresses] were even investigated?" *Id.* at 201. Mr. Parrado replied:

> In some of the partial medical records I looked at, there wasn't any evidence of any conversations between the clinics and the

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[21] While Mr. Parrado referred to Florida law "at the time," Florida law still requires that the face of a controlled substance prescription contain "[t]he full name and address of the person for whom . . . the controlled substance is dispensed." Fla. Sta. § 893.04(c)(1)(2015).

[22] Here again, Respondent objected to the testimony as "rank speculation" for which there was "no foundation." Tr. 196. He also argued that it was beyond scope of the Government's Prehearing Statement. *Id.* The ALJ overruled the objection.

As for Respondent's objection on the ground that the testimony was "rank speculation," given that Mr. Parrado testified and the prescriptions show that: (1) These two patients had the same last name, (2) provided addresses which suggested that they lived near each other, and (3) their prescriptions bore sequential prescription numbers, Mr. Parrado's testimony was a permissible inference. In any event, even if the patients did not travel together, each of these prescriptions presented red flags.

Moreover, even acknowledging that the Government did not disclose that Mr. Parrado would testify that these two persons could have travelled to Superior together, the Government nonetheless disclosed that it intended to elicit testimony regarding Respondent's filling of multiple prescriptions for patients who travelled long distances to obtain their prescriptions. ALJ Ex. 1, at 2–3 (No. 15–6); ALJ Ex 7, at 3–5 (No. 15–6). *See also supra* note 12 (collecting cases).

[23] Here too, Respondent objected that Mr. Parrado "ha[d] no idea what people who come into a pharmacy have in their pocket or they don't." Tr. 199–200. Respondent thus contended that Mr. Parrado's testimony was speculation and was outside the scope of the Prehearing Statement. *Id.* at 200. The ALJ stated that he noted the objection and that he did not need Respondent to tell him "what should be or should not be allowed in this hearing." *Id.* The ALJ then explained that he had made his ruling and instructed the Government to ask its next question. *Id.*

I agree with Respondent that this testimony was speculative because the patients could well have paid for their prescriptions with credit cards. However, the prescriptions list their respective prices as $833 (RX 452157), $952 (RX452156), and $833 (RX452155). GX3, at 13–15. Regardless of the method of payment used to purchase them, Mr. Parrado testified that the cost of the prescriptions was also a red flag.

[24] This prompted the same objection by Respondent and the same ruling. Tr. 200.

> pharmacist.[25] Also, this is one of the things I got out of the partial medical records, that there wasn't any evidence that they had even talked with the pharmacy. And there was nothing here being documented either.

Id.

Mr. Parrado then opined that it "would be outside the standard of care for a pharmacist to fill these without having resolved the red flags before dispensing." *Id.* Asked to opine on whether, based on the prescriptions and records he reviewed, the pharmacists "exercise[d] their corresponding responsibility to ensure that a prescription for a controlled substance was issued for [a] legitimate medical purpose," Mr. Parrado answered: "[n]ot that I can tell from the records shown to me." *Id.* at 201–02.

The Government then questioned Mr. Parrado about the remaining prescriptions in its Exhibit 3. These included a prescription for 240 oxycodone 30 issued on December 10, 2011 to J.M.; as with the other prescriptions, the prescriber had not written the patient's address on the prescription but the prescription contained a small sticker listing J.M.'s address as Lenoir, Tennessee. GX 3, at 22 (No. 15–6). Asked if the prescription raised any red flags, Mr. Parrado noted J.M.'s address and explained that his "first concern" was the "person coming from Tennessee." Tr. 202. Mr. Parrado identified additional red flags presented by the prescriptions, including the physician's failure to include the patient address on the prescription, that the quantity of 240 pills was a "very high dose" for oxycodone 30, that the prescription came "from the same clinic," and that it cost $1,155. *Id.* Mr. Parrado then explained that "[t]hose are all red flags that I could not have resolved." *Id.*

However, when asked by the Government if he could tell who filled the prescription, Mr. Parrado testified that the prescription bore the initials "CD," thus indicating "the pharmacist responsible" for the script; he then added that "there's a scribble on the front from somebody that canceled the prescription." *Id.* at 203. Moreover, the prescription has two diagonal lines drawn through it, along with a circle with the letter "C" in bold, and while there is a copy of the dispensing label attached to the back, *see* GX 3, at 22, the Government offered no further evidence to clarify whether the prescription was actually dispensed.

Next, the Government asked Mr. Parrado whether the prescriptions (reproduced at GX 3, at 17–18), which are dated August 6, 2011 and bear sequential prescription numbers presented any red flags. Both of these prescriptions were issued by Dr. S.A.H., a physician at the same 24th Century Medical Center in Tampa, to two persons (E.P. and R.B.) for 150 and 140 tablets respectively of oxycodone 30. GX 3, at 17–18. Here too, the front of each prescription lacked the patient's address. *See id.* However, each prescription bore a sticker listing the patient's address, and the stickers indicated that E.P. and R.B. lived at the same street address in Milton, Florida. *See id.*

Asked by the Government whether the prescriptions presented any red flags, Mr. Parrado identified the patients' addresses and added that "Milton, Florida is way in the [w]estern panhandle of Florida. It's well over 400 miles" to the pharmacy. Tr. 204.[26] Mr. Parrado noted that "both of them seem to have the same address." *Id.* However, he then testified that the driver's license that was in R.B.'s "partial medical records" listed his address as being in a different city (Pace, Florida) than Milton. *Id.* at 205. Mr. Parrado explained that the disparity between the address on the prescription and the address on the driver's license "caused me concern that they weren't looking very closely." *Id.* at 205–06.

After noting that E.P.'s prescription cost $562 and R.B.'s prescription cost $525, Mr. Parrado testified that "two people from one address paying over $1,000 would be a red flag from somebody coming . . . from 400 miles away." *Id.* at 206. He further noted that both prescriptions were written by the same physician and were for the same drug and in essentially the same quantities. *Id.* Mr. Parrado then testified that he had seen "no documentation anywhere" that Superior I's pharmacist resolved the red flags, including in the "partial medical records," which contained "no evidence that there was any conversation between the pharmacy and the physician['s] office." *Id.* at 206–07.

Next, the Government asked Mr. Parrado about a prescription issued by Dr. V.S. (also of the 24th Century Medical Center) and dispensed on December 2, 2011 to B.W., for 200 tablets of Dilaudid (hydromorphone) 8 mg. *See* GX 3, at 21; Tr. 207. Here again, the prescription lacked the handwritten patient's address but contained a sticker which listed B.W.'s address as being in Fort Ogden, Florida. GX 3, at 21.

Asked if the prescription presented any red flags, Mr. Parrado testified that there were multiple red flags, including that "it's a very, very potent drug" and that the quantity was for 200 pills. Tr. 208. Continuing, Mr. Parrado testified that:

> I have never seen a prescription in my 41 years as a pharmacist for a quantity like that of . . . Dilaudid 8 milligrams as being dosed at every . . . three to four hours.
>
> Which would be six to eight times a day. So 48 to 72 milligrams . . . would be the daily dose for a drug that the recommended upper dose be probably 24 milligrams.
>
> So it's a much higher dose then [sic] what I have ever seen as a pharmacist. And that would have caused me serious concern that I had to resolve before I could do anything, period.
>
> The fact that they came a long way, again, from Fort Ogden, from that same clinic that I'm seeing all these prescriptions from, would cause me not to be able to resolve that red flag.

Id. at 208–09.

Mr. Parrado was then asked whether a prescription (GX 3, at 19) for 196 Dilaudid 8 mg issued by Dr. P.C. and dispensed on December 1, 2011 to R.L. (Largo, Fl.) also presented red flags. Tr. 209. Mr. Parrado testified that the quantity and dosing raised the "exact same concern" as the dosing was "well outside the recommended upper dosage of that drug." *Id.* Continuing, he explained: "And I don't see anything where that was resolved to establish that the patient had developed a tolerance to that drug to avoid the respiratory depression that would have been inherent at that dose." *Id.*

Asked whether R.L.'s address in Largo was also a red flag (here too, the patient's address had not been written on the prescription but had been added by a sticker), Mr. Parrado testified that the distance was 20 to 25 miles. *Id.* at 209–10. While he acknowledged that this was not "a very long distance," he explained that "the fact that there's so many coming from outside the area just starts compounding the fact that this is almost . . . like a destination clinic or destination pharmacy where people know to go there." *Id.* at 210. Mr. Parrado then testified that he found no evidence that Superior I's pharmacist attempted to resolve the red flags.

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[25] On cross-examination, Mr. Parrado testified that he had been given the partial medical records after the New Year's holiday. Tr. 357–58.

[26] Respondent's counsel objected that the testimony was outside the scope of the Government's Prehearing Statement and was rank speculation. Tr. 204–5. The ALJ overruled the objection. *Id.* at 205. Here again, the Show Cause Order specifically alleged that "[o]n August 6, 2011, one or more Superior I pharmacists dispensed large and substantially similar quantities of thirty milligram tablets of oxycodone to two customers, E.P. and R.B., both of whom resided at the same address in Milton, Florida, which is located approximately four hundred and forty nine miles (449) from Superior I's location." ALJ Ex. 1, at 2 (No. 15–6). While this alone provided adequate notice, the Government's Prehearing Statement further advised that "Mr. Parrado will further testify that, on August 6, 2011, Respondent dispensed large quantities of thirty milligram oxycodone to two individuals, E.P. and R.B., who resided at the same address in a city located more than 440 miles . . . from Respondent's pharmacy." ALJ EX. 7, at 4 (No. 15–6). The ALJ thus properly overruled the objection.

As for the prescription (GX 3, at 20), which was issued by Dr. R. (also of 24th Century) to C.L. for 224 Dilaudid 8 mg on December 1, 2011 and filled the same day, Mr. Parrado again found the quantity to be a red flag, testifying that this would be "a lethal dose to an opioid naïve patient." Tr. 211. He then explained that "there's nothing here to show that the patient has developed a tolerance to this drug." *Id.*[27] As for the prescription (GX 3, at 23), which was issued by Dr. V.S. (of the same clinic) to M.A. for 224 Dilaudid 8 mg on December 2, 2011 and filled the same day, Mr. Parrado testified that the "very high dose" was a red flag and that there was no evidence that the patient had developed tolerance to the drug. Tr. 212.

Concluding its direct examination of Mr. Parrado regarding the Superior I prescriptions, the Government asked if he had an opinion as to whether the pharmacists who dispensed the prescriptions knew or had reason to know that they were issued without a valid doctor-patient relationship. Tr. 220–21. After the ALJ overruled Respondent's objection,[28] Mr. Parrado explained:

> There's no documentation that I saw that there was any conversation with a physician determining that. Because at these doses there would had to have been conversation determining tolerance. There would have been conversation determining medical need at this dosing.
>
> So at that point I would have had a question in my mind, as a pharmacist filling or being presented with this prescription, that there may have been . . . not a very good valid patient–doctor relationship going on at that point in time.

Id. at 221–22.

On cross-examination, Mr. Parrado acknowledged that he could not offer an opinion as to whether any of the patients, whose prescriptions were provided in GX 3, were opioid naïve. Tr. 235–36. Asked whether it was true that he had no knowledge as to the procedures used at Superior I to revolve red flags, Mr. Parrado answered that "[n]othing that was documented on the prescriptions showed that anything had been done." *Id.* at 237. After acknowledging that "there's nothing that mandates where [documentation] has to be," he also acknowledged that if the resolution of the red flags was documented someplace other than on the prescription itself, the documentation wasn't provided to him, and thus he does not know whether it exists or not. *Id.* at 237–38.

While Mr. Parrado testified that he knew one of the pharmacists who worked at Superior I, he stated that he had not spoken with her about any of the prescriptions. *Id.* at 246. Nor has he discussed with any of Superior I's pharmacists the policies or procedures the pharmacy had in place from January 1, 2011 through February 4, 2013, or currently has in place, for identifying diversion and for documenting the resolution of red flags. *Id.* at 246–47.

Mr. Parrado further testified that he asked DEA "for complete profiles on all these patients" but was told to look at only the prescriptions. *Id.* at 247. He then testified that he believed the Agency had the profiles because he had seen some of them in the DEA's office. *Id.*

Mr. Parrado testified that he had not consulted with any other pharmacists in forming his opinions. *Id.* at 248. He also testified that he did not speak with any of the prescribers of the 25 prescriptions or with the patients who received them. *Id.* at 249. He then testified that he did not know what training or experience the prescribers had. *Id.* at 250.

Asked by Respondent whether, based on the materials provided to him by DEA, he knew if Superior I's pharmacists had called the prescribers "to discuss any issues related to the patients or the prescriptions," Mr. Parrado answered that "did not see anything to that effect." *Id.* at 251. He then testified that if "[i]t wasn't documented[,] [i]n my mind, they didn't do it." *Id.* However, Mr. Parrado acknowledged that he did not know if this was documented other than on the prescriptions. *Id.* at 252.

Mr. Parrado did not know whether Superior I kept a paper file which included medical records on their patients. *Id.* at 254. He also did not know if Superior I's pharmacists obtained copies of MRIs, X-Rays and CT scans. *Id.* He then testified that:

> In the partial patient records that I did receive, there was evidence of some MRIs. What struck me was that these MRIs were old and not ordered by the physician who was writing these prescriptions, which would have been a red flag to me. Some of these MRIs were two/three years old. They were ordered by someone else.
>
> There were some . . . MRIs, reports didn't even have a referring prescription on it. That would have concerned me as a pharmacist filling that prescription.

Id. at 254–55.

Respondent then asked Mr. Parrado if, based on the information provided to him, he was "aware that the pharmacists were obtaining copies of radiographic studies [and] reports of radiographic studies?" *Id.* at 255. Mr. Parrado answered:

> No, I didn't say I saw it in the pharmacy records. I saw it in the medical records. If the pharmacist would have had access to that, that would have presented another red flag in the fact that that was an old record ordered by someone else. That would have raised the bar there if you will.

Id. Mr. Parrado then explained that he did not know the source of the medical records.[29] *Id.*

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[27] In response to the Government's question whether the fact that these two prescriptions were presented the same day raised "[a]ny additional red flags," Mr. Parrado testified that "[t]hat's another pattern prescribing red flag. To me." Tr. 211–12. I conclude, however, that two prescriptions do not establish pattern prescribing.

[28] Respondent objected on the ground that "[t]here's no opinion summarized anywhere in the Government's [P]re-hearing [S]tatement . . . that relates to whether or not . . . the pharmacist knew or should have known that those prescriptions were issued. And it's outside his area of expertise. It's nothing but rank speculation." Tr. 221.

Even assuming that the first ground for objection was that the Government did not provide notice that it intended to ask whether the pharmacists knew or should have known that the prescriptions were issued without a valid doctor-patient relationship, in its Prehearing Statement, the Government advised that Mr. Parrado "will testify that, based on his expertise, training, and experience, and based on his review of the evidence summarized above, Respondent's pharmacists failed to exercise their corresponding responsibility to ensure that prescriptions for controlled substances were issued for a legitimate medical purpose in the usual course of professional practice." ALJ Ex. 7, at 5. Asking whether the prescriptions "were issued without a valid-doctor patient relationship" is just another way of asking whether the prescriptions "were issued for a legitimate medical purpose in the usual course of professional practice," as a physician must establish and maintain a valid doctor-patient relationship to act in the usual course of practice and to issue a prescription for a legitimate medical purpose.

Nor was it beyond Mr. Parrado's expertise to opine on whether the prescriptions were issued outside of a valid doctor-patient relationship. *See United States* v. *Hayes,* 595 F.2d 258, 261 & n.6 (5th Cir. 1979) ("[A] pharmacist can know that prescriptions are issued for no legitimate medical purpose without his needing to know anything about medical science."). Indeed, pharmacists are expected to review the patient record and each prescription for therapeutic appropriateness and identify, *inter alia,* over-utilization, incorrect drug dosage, and clinical abuse/misuse. Fla. Admin Code r.64B16–27.810(1). A pharmacist is obviously required to be able to determine when a prescription calls for the dispensing of such potent narcotics as oxycodone or Dilaudid in quantities that far exceed recommended upper dosages and would be lethal in an opioid naïve patient, let alone when a patient presents such other red flags of abuse or diversion, such as travelling long distances to obtain narcotics.

[29] Subsequently, the lead Investigator testified that the medical records had been obtained

Continued

Mr. Parrado acknowledged patients become dependent and develop tolerance to opioid analgesics and that there is no upper limit as to the quantity or dose that can be prescribed. *Id.* at 260. He also acknowledged that he did not know if any of the patients who received the prescriptions in GX 3 worked in Tampa. *Id.* He also conceded that the patients "were seeing the physicians regularly over a good period of time." *Id.*

Continuing, Mr. Parrado acknowledged that there is an expressway which runs from Spring Hill to Tampa, and that people may commute from the former to the latter for work. *Id.* at 261. Mr. Parrado testified that this red flag would have been resolvable if the question had been asked and answered. *Id.* at 262.

Next, Mr. Parrado testified that a pharmacist can add an address to a prescription if "you've checked with the physician and gotten the correct thing and that matches what the patient is telling you." *Id.* at 263. He then acknowledged that he did not attempt to determine if any of the prescriptions in GX 3 were necessary for the treatment of chronic or recurring disease. *Id.* at 264.

On re-direct, Mr. Parrado was asked whether the one patient profile he was provided with was for P.D. (GX 3, at 24) and whether the profile showed that there was a gap in care. Tr. 268. Asked to describe what was on the document, Mr. Parrado testified that:

> [t]there was a list of dates for Mr. P.D. that showed the dates he had prescriptions filled for this drug and there was a gap of two months in there which, as a pharmacist, anybody that stops taking opioids or if I don't know he's continued taking opioids, at that point I can't fill a further prescription till I've established that.
>
> He could have been in jail. He could have been in a rehab unit. It is well-documented that patients that have gone into these things, gone back in the community and accessed a prescription at the old dosage they were on would kill them and it has killed them.

Id. at 269–70.[30] Asked by the Government whether when he reviewed this document, he saw any indication that red flags had been resolved or explained, Mr. Parrado answered "no." *Id.* at 271.

Questioned by the ALJ as to where he would document the red flags presented by a prescription, Mr. Parrado testified that: "I would have identified the red flags that concerned me when the prescription was presented. I would have noted that on the back and I would have noted what I did to resolve each one of those if there was more than one." *Id.* at 273. Mr. Parrado added that "you scribble on the back and/or you write on a piece of paper and staple it to that prescription." *Id.*

The ALJ then asked Mr. Parrado if, in his "experience working with other pharmacists, . . . they have other ways of making records . . . to keep track of the red flags and how they've been resolved?" *Id.* at 274. Mr. Parrado answered: "[n]ot in the 43 years I've been a pharmacist." *Id.*

On further re-cross, Respondent asked Mr. Parrado: "Not all pharmacists document in the same way that you do, do they?" *Id.* Mr. Parrado answered: "[a]s a Board of Pharmacy member, I would have expected them when they came before the Board to show me that documentation. It was always on the prescription. It's always on that prescription record somehow." *Id.* Noting that Mr. Parrado had not been on the Board of Pharmacy for some time, Respondent then asked if he had "ever seen in your 43 years[,] pharmacists document the same information in different ways?" *Id.* at 275. Mr. Parrado answered: "I've seen them document in different ways but always on the prescription." *Id.*

The Superior II Prescriptions

With respect to the Superior II prescriptions, Mr. Parrado testified that he reviewed them in the same manner as he did the Superior I prescriptions. *Id.* at 277. He then proceeded to identify various red flags presented by the prescriptions.

The first of these was a prescription issued by Dr. H.V.D. (also of the 24th Century Medical Center) to J.T. of Fort Meyers, Florida, for 280 oxycodone 30. GX 3, at 1–2 (No. 15–7). Here again, the patient's address was left blank and the address was provided by a sticker, which was affixed to the front of the prescription. *Id.* at 1. Mr. Parrado testified that prescription presented the following red flags: The drug having "a high potential for abuse"; the "very large quantity" and "the dosing at a very high rate, well above . . . 80 milligrams a day"; the "patient travelling from Fort Meyers, which is . . . 150 miles or so from Tampa"; and the patient paying $1,260 cash for the drugs. Tr. 277–78.[31] Mr. Parrado then testified "there was nothing on the prescription to show me that these things had been discussed." *Id.* at 279.

The second prescription was issued on December 2, 2011 by Dr. R. (the same Dr. R. of 24th Century), to R.B. of Milton, Florida (the same R.B. discussed in the Superior I findings) for 168 oxycodone 30. GX 3, at 3–4 (No. 15–7). Here again, the patient's address was left blank and the address was provided by a sticker, which was affixed to the front of the prescription. *Id.* at 3. After Mr. Parrado identified R.B. as being one the persons who filled a prescription at Superior I which presented red flags, the Government asked him to also look at the prescriptions reproduced at pages 5–6 of the exhibit. The latter prescription was also issued on December 2, 2011 by Dr. V.S. (also of 24th Century) to E.P., who again used R.B.'s address as her address; the prescription was also for 168 oxycodone 30. *Id.* at 5–6. Of further note, R.B.'s and E.P.'s prescriptions had sequential RX numbers. *Id.*

Asked if these prescriptions presented any red flags, Mr. Parrado testified that "[t]hese were the same two patients that had gotten prescriptions filled at the other pharmacy, both with the same Milton, Florida address, both paying $924 in cash, travelling a long way, very high dosing, all the same concerns I had with the previous prescriptions." Tr. 280–81. He also observed that the prescriptions "were filled consecutively" and that the dispensing labels show that the same pharmacist (M.F.) filled the prescriptions, and that these circumstances would have caused him concern. *Id.* at 282–83. And Mr. Parrado further testified that he saw no evidence that the pharmacist attempted to resolve the red flags. *Id.* at 283.

The next prescription was issued on September 18, 2012 by Dr. V.S. (the same Dr. V.S. who had worked at 24th Century) to L.P. of Jacksonville, for 168 oxycodone 30. GX 3, at 7–8. Mr. Parrado testified that the prescription presented multiple red flags including "the drug," the "very high quantity," that the patient was "coming from Jacksonville . . . over 200 miles" from Tampa, and that the patient was "paying $1,344 in

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pursuant to a subpoena issue to the 24th Century Clinic and had been provided to Mr. Parrado by Government Counsel. Tr. 578, 589–90.

[30] At this point, Respondent objected, arguing that if Mr. Parrado was going to talk about this document, the Government should be required to "produce the document so that we can see what it is that he's talking about. You know, he's talking about some amorphous document." Tr. 270. He also argued that the testimony was outside the scope of either cross examination or the Prehearing statement. *Id.* While the ALJ disagreed that it was outside the scope, he explained that because there was "no document in front of him" and he was "relying on the frailties of human memory," he was not going to give this testimony "a whole lot of weight." *Id.* at 271.

[31] Respondent objected to Mr. Parrado's testimony as to the price, asserting it was beyond the scope of the Pre-hearing Statement because it did not specifically identify "the pricing issue" as being one of the red flags associated with the prescription. Tr. 278. The Government did, however, identify that it intended to elicit testimony on the issue of "individuals playing [sic] high prices for prescriptions . . . with cash." ALJ Ex. 7, at 3 (No. 15–7).

cash." Tr. 284. Mr. Parrado then testified that there was "nothing documented" regarding the pharmacist's attempt to resolve the red flags. *Id.*

After Respondent "object[ed] to the repetitive nature of this," the ALJ asked Mr. Parrado if he had found "the same kinds of red flags" throughout the Exhibit. *Id.* at 285. Mr. Parrado answered "[y]es." *Id.* The ALJ then asked Mr. Parrado if he had also found that "the failure to resolve the red flags is documented on the documents there?" *Id.* Mr. Parrado answered "[y]es." However, after the ALJ asserted that "[t]hat seems to address all of Exhibit 3," the Government advised the ALJ that there were "some differences." *Id.*

The Government then questioned Mr. Parrado about two prescriptions which were issued on May 22, 2102 by Dr. C. (also of 24th Century) to L.B. of Dover, Florida, which the latter filled the same day. GX 3, at 11–14. The prescriptions were for 168 oxycodone 30 and 84 Dilaudid 8 mg. *See id.* Asked by the Government whether the combination of these two drugs raised a red flag, Mr. Parrado testified that "that's a major red flag in that you have two immediate use opioids being dispensed at the same time. The practice is never to dispense two immediate use opioids at once, at the same time for the same patient." *Id.* at 286. Mr. Parrado then testified that both of the drugs were immediate release, and upon being asked if there was a way to resolve this red flag, Respondent objected to the testimony, arguing that it was beyond the scope of the Government's Prehearing Statement. *Id.* at 287.

The ALJ overruled the objection, explaining that "I'd like to know." [32] *Id.* Mr. Parrado then testified that he could not resolve the red flag, and that while it was proper therapy to prescribe a "long-acting opioid, like OxyContin" and an immediate release drug "such as hydromorphone for breakthrough," using "two immediate use opioids[,] [y]ou just don't do that." *Id.* Here again, Respondent objected on the ground that the opinion was beyond the scope of Mr. Parrado's expertise because he is not a physician. *Id.* at 287–88. The ALJ overruled the objection. *Id.* at 288.

On May 22, 2012, Respondent filled prescriptions for 168 oxycodone 30 and 56 Dilaudid 8 issued by Dr. S.A.H. (of 24th Century) to V.B., who has the same last name and lived in the same town as L.B.[33] GX 3, at 15–18. Asked whether "seeing these prescriptions together," there were "additional red flags," Mr. Parrado testified that "the fact that two people from essentially the same address were coming together with the same last name for the same drugs which were two immediate use opioids from the same clinic . . . I would have found that unresolvable." Tr. 289–90. Mr. Parrado then testified that he found no evidence that the red flags were resolved. *Id.* at 290.

On October 22, 2012, Dr. V.S. (who, according to the prescription was then working at the MD Plus Clinic in Lakeland), issued a prescription for 168 oxycodone 30 to J.P., whose address (which again was not written on the prescription) was in Ft. Walton Beach, Florida; Respondent filled the prescription the same day. GX 3, at 19–20. Upon being asked "what kind of route J.P. [would have] follow[ed] if he came from home, went to the doctor's office in Lakeland and then went to Tampa" to fill the prescription, Respondent objected on the ground that the testimony would be speculative because Dr. V.S. could legally prescribe at any place in the State. Tr. 293–94. After the ALJ overruled the objection, Mr. Parrado testified that while he did not "know the exact route [J.P.] took . . . the triangle between . . . the three places is very large [and] would have to be resolved." *Id.*

On October 23, 2012, Dr. V.S. (of the MD Plus Clinic) issued a prescription to K.B. of Jacksonville, for 168 oxycodone 30; Respondent filled the prescription on November 7, 2012. GX 3, at 21–22. On October 22, 2012, Dr. R.R. (of the 24th Century Medical Center) issued a prescription to R.B. of Milton for 168 oxycodone 30; Respondent filled the prescription on November 1, 2012. *Id.* at 23–24. Mr. Parrado testified that both prescriptions presented the same red flags that he had previously discussed. Tr. 295–96.

On November 5, 2012, Dr. H.D. (of the 24th Century Medical Center) issued a prescription to J.S. of Panama City Beach, for 180 oxycodone 30; Respondent filled 120 tablets of the prescription the same day. GX 3, at 25–26. Asked where Panama City Beach is in relation to Tampa, Mr. Parrado testified that it is located in the "extreme western part of the Florida panhandle" and 450 miles from Tampa. Tr. 297.

Notably, the prescription contains a handwritten notation: "120 per pat" with the rest of the word obscured by the address sticker, below which is the date and time. GX 3, at 25. According to Mr. Parrado, "this was the only form of any kind of notation or documentation I saw on any of the records showing that they did document at one point and the only thing they documented was that they shorted the person pills." [34] Tr. 298. Mr. Parrado further noted while the address on prescription listed Panama City Beach as J.S.'s town of residence, the sticker attached to the prescription, as well as the dispensing label, listed her town of residence as Port Charlotte, which is in the "opposite direction" from Tampa. *Id.*

On November 5, 2012, Dr. R.R. (24th Century) issued a prescription to A.R. for 180 oxycodone 30; Respondent filled the prescription the same day. GX 3, at 27–28. While the prescription lists the patient's address as Lawtey, Florida, both the address sticker attached to the prescription and the dispensing label list A.R.'s address as in Gainesville, Florida. *Id.* Over Respondent's objection (on grounds of no notice), Mr. Parrado testified that this was an additional red flag and the "difference . . . should have been documented." Tr. 300–01.

On April 23, 2012, Dr. S.A.H. (24th Century) issued a prescription to T.P. of St. Augustine, Florida for 180 oxycodone 30; Respondent filled the prescription the same day. GX 3, at 29–30. Noting that Saint Augustine is located "just below Jacksonville" in "the upper northeast corner of Florida," Mr. Parrado testified that "the distance" between T.P.'s residence and Respondent was a red flag. Tr. 301–02.

Also on April 23, 2012, Dr. P.C. (24th Century) issued a prescription to A.W. of Mayo, Florida, for 200 oxycodone 30; Respondent filled the prescription the same day. GX 3, at 31–32. Mr. Parrado testified that Mayo is located 150 to 200 miles from Tampa and that this was a red flag "along with all the other things," including "the drug and the price paid," which was $1,400. Tr. 302–03; GX 3, at 32.

On April 23, 2012, Dr. P.C. issued a prescription to D.T. of Gainesville for 190 oxycodone 30; Respondent filled the prescription the same day. GX 3, at

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[32] As discussed above, the Government failed to provide Respondent with constitutionally adequate notice on this issue. *See, e.g., Pergament United Sales,* 920 F.2d at 135 ("The primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the complaint and fashioning an explanation that refutes the charge of unlawful behavior.").

[33] Mr. Parrado noted that while the prescriptions for L.B. and V.B. indicated that they lived on different streets, they had the same house number. Tr. 288. While Mr. Parrado then suggested that "may have been just a typo," *id.*, the Government offered no further evidence to corroborate this testimony.

[34] Mr. Parrado further testified that it is common practice to make a note on the prescription when pharmacist does not provide a patient with the entire quantity of the prescription. *Id.* at 299.

33–34. Also on April 23, Dr. S.A.H. issued a prescription to J.S. of Tallahassee for 168 oxycodone 30; Respondent filled the prescription the same day. *Id.* at 35–36. Mr. Parrado testified that neither prescription raised "any additional red flags" beyond those he had previously discussed. Tr. 303. However, on further questioning, he testified that Tallahassee is 250 to 260 miles from Tampa.[35] *Id.* at 303–04.

On November 2, 2012, Dr. R.R. issued a prescription for 112 Dilaudid 8 mg to T.N., which Respondent filled the same day. GX 3, at 37–38. Of note, while the prescription as prepared by Dr. R.R. listed T.N.'s address as being in Port Salerno, Florida, both the address sticker placed on the front of the prescription and the dispensing label listed an address in Gainesville. *See id.* Mr. Parrado testified that this was a red flag, as was the high dose of the prescription (32 mg per day), which was "above the 24 milligram upper dose recommendation." Tr. 304.

The final prescription in the exhibit was issued on November 5, 2012 by Dr. H.D. to K.P. of Spring Hill for 140 Dilaudid 8 mg. GX 3, at 39–40. Asked the same question as with previous prescription ("How about the drug and the amount?"), Mr. Parrado testified: "[t]he answer will be the same." Tr. 304. Thereafter, the Government moved Exhibit 3 into evidence in the Superior II matter, and the ALJ admitted the exhibit. *Id.* at 305.

The Government then moved to admit into evidence its Exhibits 4 and 14. *Id.* The former is a compilation of 25 additional prescriptions for oxycodone 30 and Dilaudid 8 mg, which was offered to show additional instances in which patients presented the "red flag of long distance" between their residence, the prescriber, and Superior II. *Id.; see also* GX 4 (No. 15–7). The latter is a collection of MapQuest maps and printouts showing the distances between the patient's residence, the prescriber, and Superior II. *Id.; see also* GX 14 (No. 15–7). Both exhibits were admitted over Respondent's objection.[36] Tr. 305–06.

As for the prescriptions in GX 4, Mr. Parrado testified that they all presented the red flag of the patients travelling long distances. Tr. 308. He further testified that he used Google to "get an approximation of the mileage" for those cities for which he did not know the exact mileage. *Id.* at 310.

Asked by the Government whether he had seen any evidence that Superior II's pharmacists attempted to resolve the red flags presented by the prescriptions in both its Exhibits 3 and 4, Mr. Parrado testified that "[t]he only documentation I saw was that shortage of tablets. That's the only thing I saw documented anywhere." Tr. 312. With respect to these prescriptions, Mr. Parrado then testified that he did not "see any evidence" that the dispensing pharmacist had complied with his/her corresponding responsibility to ensure that prescriptions were issued for a legitimate medical purpose. *Id.*

The Government concluded its direct examination of Mr. Parrado, asking him—over Respondent's objection—whether the pharmacists, who filled the prescriptions in GXs 3 and 4, "knew or had reason to know that the prescriptions were being issued without a valid doctor/patient relationship?" *Id.* at 313–14. Mr. Parrado answered:

> All these red flags would have caused me concern to where I had to call that physician to verify all these things.
>
> And at that point I would have to use my professional judgment and whether or not even though possibly faced with what could ostensibly be a valid prescription I should know or either knew or should have known that these were being used . . . for not a legitimate medical purpose, just based on all the red flags that are present.
>
> So even if the doctor had told me, yes, he did fill it, I would still, I still would not have filled them.

Id. at 314–15.

On cross-examination, Mr. Parrado adhered to his earlier testimony that if the resolution of a red flag was not documented on the prescription, "it wasn't done." *Id.* at 316. While Parrado acknowledged that he did not know whether Florida law requires that this be documented on the prescription, he testified that "[i]t's been standard practice since I've been practicing for 43 years." *Id.* He further acknowledged that DEA does not require that the resolution of a red flag be documented on the face of the prescription. *Id.* at 318. And he also acknowledged that in rendering an opinion as to whether another pharmacist had properly exercised his professional judgment in deciding to dispense a controlled substance, it is important to understand the circumstances, including whether the pharmacist has a history with the prescriber of the prescription. *Id.* at 321.

Asked by Respondent whether he "wouldn't think twice about" a prescription he received from a reputable prescriber which was missing the patient's address, Mr. Parrado testified that "I would do something to address that and fix it." *Id.* Asked if he would then go into his pharmacy software and use the information to put an address label on the prescription and that this would not cause him "to be concerned about diversion," Mr. Parrado answered: "Not if I knew the patient. And there's always a circumstance where it [the prescription] could be good." *Id.* at 321–22.

When then asked whether "one of those circumstances would be if you knew the prescribing practitioner and . . . . [his] practice[] and . . . protocols and . . . knew that when you called them [he] answered your questions about the diagnoses and the reasons for things," the ALJ, without any objection by the Government, stated that he would not allow Mr. Parrado to answer the question because there was "no evidence that the Respondent, through any of its pharmacists, did that." *Id.* at 322. Even after Respondent argued that it was a hypothetical question and that Mr. Parrado "was proffered as an expert" and had testified that he had asked for additional information from DEA and been denied it, the ALJ adhered to his ruling. *Id.* at 322–23.

However, Mr. Parrado subsequently agreed with Respondent that in trying to determine whether a red flag had been resolved, it is "important to know what the pharmacist knew about" the patient. *Id.* at 324. Mr. Parrado testified that he had asked for the patient profiles for the Superior II patients and that the Government told him not to look at those. *Id.* at 324–25. Mr. Parrado then acknowledged that a patient profile would show the complete history of prescriptions filled by the pharmacy in the period for which it was run and would show whether the patient was also receiving non-controlled drugs. *Id.* 325. He also acknowledged that the patient profile would be important in determining whether the patient was opioid naïve or tolerant. *Id.*

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[35] Respondent objected to Mr. Parrado's testimony regarding the distances from Mayo to Tampa and Tallahassee to Tampa on the ground that this testimony was not disclosed in advance of the hearing. Tr. 302–03. In its Pre-Hearing Statement, the Government did disclose that Mr. Parrado "will . . . testify regarding large quantities of oxycodone distributed by Respondent on April 23, 2012, to at least twelve persons . . . and four of them (T.P., A.W., D.T., and J.S.) resided more 100 miles from Respondent's pharmacy." ALJ Ex. 7, at 5 (No. 15–7). Respondent thus had notice that the distance between it and the residences of the patients would be at issue even if the Government did not disclose that Mr. Parrado would testify as to the precise distances.

[36] With respect to the MapQuest printouts, Respondent did not object based on authenticity, but rather on lack of foundation, arguing that "there are ways to set parameters to avoid highways, to take the shortest route, to take the fastest route." Tr. 307. The objection is not without some merit. However, given the distances of the patients from the prescribers and Superior, any differences in mileage or driving time which would be caused by choosing between these two parameters is not significant enough to be material.

Mr. Parrado then testified that he was given some "partial medical records," and that these showed that "these people were on multiple controlled substances [and] not just the prescriptions that were given to me." *Id.* He then added that there were "multiple people from the same address getting the exact same cocktails of these drugs." [37] *Id.* at 325–26.

Asked if his opinions were based on these medical records, Mr. Parrado testified that the medical records did not form his opinions but "just reinforced" them, because he did not "see any documentation of conversations between the pharmacy and the clinic" and the records "showed on a lot of these patients the cocktails." *Id.* at 326. After Mr. Parrado testified that the medical records were those "of the prescribing physician," Respondent attempted to ask if he knew whether a physician is supposed to note a conversation with the pharmacist in the chart. *Id.* The ALJ barred the question, even in the absence of an objection of the Government, reasoning that there was no evidence that any of Superior II's pharmacists had called the prescriber. *Id.* at 327.

Mr. Parrado then acknowledged that there is "no upper limit on the amount of an opioid that a patient can develop a tolerance to" and that there is no federal limit on the quantity of a drug that can be prescribed. *Id.* He further testified that whether a prescription is medically necessary is patient specific and depends on such factors as tolerance, the condition causing the pain, and the duration, intensity and frequency of the pain. *Id.* at 330.

Asked whether it was *per se* unlawful to fill an oxycodone 30 prescription, Mr. Parrado testified that "I would have to evaluate each prescription individually and know that . . . that patient had developed that tolerance . . . before I fill it." *Id.* at 331. Then asked whether "[o]xycodone 30 standing alone is not an indicator that a prescription" lacks a legitimate medical purpose, Mr. Parrado answered: "Well, it's the leading drug of abuse on the street. So that is the first potential for a red flag." *Id.*

Mr. Parrado acknowledged that patients have the right to pay for their prescriptions in cash and that in some States, the law requires a pharmacy to allow a patient to pay in cash. *Id.* at 332. Mr. Parrado then testified that it is "not so much the paying cash, it's the quantity of cash that raised the red flag to me." *Id.*

While Mr. Parrado agreed that physicians may use a particular drug as their default option in treating a patient such as in prescribing a cholesterol-lowering medication, he disagreed that this practice also applies to pain management. *Id.* at 333. As he explained: "how you treat diabetes, blood pressure, . . . cholesterol therapy, those are relatively standard therapies. But not in pain, pain has to be individualized, starting low and going slow as you reach the proper limit" of dosing. *Id.* Respondent then asked if the fact that a prescriber tends to prescribe one drug over another for pain patients "is not necessarily indicative of diversion, is it?" *Id.* at 334. Mr. Parrado answered: "It becomes a cause for concern when it's always the number one known drug of abuse on the streets. That's where it becomes a concern. And in oxycodone and Percocet, there's a very low dose, it's only five milligrams, whereas . . . oxycodone 30 presents a different issue." *Id.*

Asked if when he verified the identity of a person filling a prescription, he would place a photocopy of the patient's identification on the prescription, Mr. Parrado acknowledged that "[a] lot of times we did," or we had "another page with it," or we "scanned it into our computer where it showed up as part of that patient's profile." *Id.* at 336. When, however, Respondent asked Mr. Parrado if "it would be appropriate for certain types of verifications and resolving of red flags to keep, say for example, a photo ID in an electronic file of a pharmacy, particularly in the age of computers," the ALJ intervened—again, in absence of an objection by the Government—and disallowed the question, explaining that "whether it's appropriate or not, there is nothing before me that suggests that that was kept." *Id.* at 337.

Mr. Parrado subsequently agreed with Respondent that "not every failure to catch a red flag is intentional" and that pharmacists can make mistakes. *Id.* at 337–38. While he agreed that a pharmacist may make mistakes in dispensing drugs, he then explained:

> The question is that it doesn't happen over and over and over and over, which was my concern in this case and the records I was looking at. Could a person come from a long distance once? Sure. Does it happen every day from a long distance multiple times? No.

Id. at 338.

Turning more specifically to the prescriptions filled by Superior II, Mr. Parrado reiterated that he did not interview any of the patients or prescribers, as well as that DEA did not provide him with any statements made by the patients or information about the patients' conditions. *Id.* at 339. Asked whether it would be appropriate for a pharmacist, who knew the address placed on the prescription by the prescriber was incorrect, to verify the patient's address and place a sticker on the prescription with the correct address, Mr. Parrado answered: "I would want to document that I had . . . addressed that question . . . and then put [the sticker] on there." *Id.* at 341. He then maintained that while the stickers were placed on the prescriptions, he did not know that the pharmacists had verified the patients' addresses. *Id.* Asked whether it is appropriate for a pharmacist to add the address to the prescription when the physician did not include it, Mr. Parrado testified: "[a]fter consultation with the physician." *Id.* at 342. When then asked if a DEA letter addressing the prescribing of schedule II drugs "says that," Mr. Parrado testified that Florida law (Chapter 893) "says that you verify with the prescriber," before acknowledging that a DEA letter "does not say that." *Id.*

Mr. Parrado agreed with Respondent that it would be permissible for a physician to prescribe pain medicine to "two people who share a residence" and who "have chronic pain due to a car accident." *Id.* at 343–44. Asked whether "if the prescriptions were legitimate, it would be permissible for a pharmacy to fill" them, Mr. Parrado answered that it would be as long as the pharmacist had resolved the red flag and documented it. *Id.* at 344.

As for the "partial medical files" he reviewed, Mr. Parrado could not answer as to how many of them were for Superior II's patients. *Id.* at 344. As for why he was provided with partial and not the full files, Mr. Parrado explained that it was his understanding that the files "came from the Respondent to DEA who sent them to me." *Id.* at 345.

Mr. Parrado acknowledged that as long as a prescriber is registered within a State, he can prescribe from anywhere in the State. *Id.* at 346. He then acknowledged that he had not looked into whether any of the prescribers had issued the prescriptions from locations other than where they were registered. *Id.* at 347.

Regarding the prescription issued to J.S. for 180 oxycodone 30 but which was only filled for 120 tablets, *see* GX 3, at 25, Mr. Parrado acknowledged that a pharmacist can change the quantity in consultation with the prescriber. Tr. 347. As for the prescription issued to T.N. for Dilaudid which listed her address as Port Salerno but the address and dispensing labels listed her address as Gainesville, GX 3, at 37–38; Mr. Parrado agreed that the prescription did not present the red flag of a different address when it was presented to the pharmacy and that the sole red flag was the distance.[38] Tr. 352. He then agreed that "it is not a red flag for a pharmacist to affix the correct address to a prescription that contains an incorrect address," before adding that he "would have documented" his reason for "changing the address." *Id.* at 353. However, on re-direct regarding the same exhibit, Mr. Parrado testified that if a patient presents a prescription which lists a different address for the patient from that in the pharmacy's records, this needs to be investigated and there was no evidence that the disparity was investigated. *Id.* at 362.

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[37] No evidence established what the cocktails were, let alone the strength and dosing of the drugs.

After Mr. Parrado noted that some of the partial medical records contained an opioid contract that required the patient to fill the prescriptions at one pharmacy, that being Respondent, he then acknowledged "that there are a number of experts who believe that the one doctor, one pharmacy, one patient is the best way to prevent diversion when it comes to pain management." *Id.* at 355. And he agreed that "[a]s long as everybody's doing their obligations," this approach is in "the best interests of the patient." *Id.* He also acknowledged that Florida law requires the use of a pain management contract, and that the contract is supposed to identify where the prescriptions will be filled. *Id.* at 356.

Evidence Regarding the Audits and Recordkeeping Allegations

Next to testify for the Government was a Diversion Investigator (DI) who participated in the execution of the Administrative Inspection Warrant at Superior I. *Id.* at 370–71. The DI testified that at the time of the hearing, he had been a Diversion Investigator for more than five years and that he had conducted approximately 130 pharmacy inspections. *Id.* at 368–69. He also testified that he had received training in how to conduct controlled substance audits as part of his training to become a DI. *Id.* at 390.

According to the DI, "we collected original prescriptions," as well as DEA 222s (schedule II order forms), invoices and inventory records. *Id.* at 372. He also "conducted the closing inventory" and "helped package the documents and all controlled substance related records."[39] *Id.* The DI testified that he conducted an audit of Superior I's handling of controlled substances and prepared a computation chart. Tr. 373; *see also* GX 4 (No. 15–6).

With respect to the closing inventory, the DI testified that this involved a count of the drugs the pharmacy had on hand at the time of the inspection and that he was assisted by the pharmacist in performing the closing inventory. *Id.* at 373–74. He also testified that he used the pharmacy's "bi-annual [sic] inventory" which was dated May 2, 2011 (beginning of business),[40] and used this as the beginning date of the audit. *Id.* at 374–75. As for the closing inventory, the DI testified that he counted the drugs on hand "with the pharmacist," and that the pharmacist attested to the accuracy of the inventory. *Id.* at 376. The DI further testified that after the warrant was executed, he requested additional records through the lead Investigator because "the bi-annual [sic] inventory" which was provided by Superior I when the warrant was executed "did not include all the drugs that were a part of the audit." *Id.* at 378. On February 11, 2013, the DI received additional inventories which included "the bi-annual [sic] inventory and . . . an in-house inventory conducted by the" pharmacy. *Id.* at 379.

The DI then explained that in conducting the audit he reviewed the purchase records, "the distribution transfers," "any returns," and "any disposition records" which included the actual prescriptions." *Id.* at 378, 410. Subsequently, with respect to the prescriptions, he supervised a team which computed the dispensings, which were counted on a monthly basis. *Id.* at 412–13. The DI also explained that each of the team members was a DI, and as such, had been trained in how to conduct an audit. *Id.* at 414.

According to the DI, "we use whatever we have as well . . . to make cross checks and to verify that there are no inconsistencies." *Id.* at 378. Still later, the DI explained that he personally cross-checked some of the monthly dispensing totals. *Id.* at 412.

The DI testified that his audit found that Superior I had shortages of multiple drugs. *Id.* at 380–382. The most significant of these were the shortages of 15,560 dosage units (du) of oxycodone 30 mg and 11,951 du of hydromorphone 8 mg. GX 4 (No. 15–6). In addition, the audit found that Superior had shortages of 946 du of hydromorphone 4 mg, 864 du of methadone 10 mg, 474 dosage units of morphine sulfate 100 mg ER, and 447 du of morphine sulfate 30 mg ER.[41] *Id.*

The DI also testified regarding the manner in which Superior I kept its Schedule II order forms (DEA 222). According to the DI, one of the order forms (GX 5, at 2) should not have been used because the pharmacist had lined out the National Drug Code (NDC) number for the drug being ordered and added a new NDC number. Tr. 383–84; *see also id.* at 386. The DI testified that according to 21 CFR 1305.15(a)(2), "any alteration or any erasure or change of description should be a cause for a DEA 222 form not to be used." *Id.* at 383. The Government then asked the DI whether a second order form (GX5, at 3) was filled out properly. *Id.* at 384. The DI answered "[n]o," and explained that "the information in regard to the number of package[s] receive [sic] . . . was omitted." *Id.*

On cross-examination regarding the altered order form (GX 5, at 2), the DI conceded that according to the regulation, the manufacturer should not have filled the order. Tr. 387. Then asked whether there was "any problem with the pharmacy having corrected the Form 222, or is the problem that the manufacturer filled the order," the DI explained that "the regulation says any alteration, any erasure, and that should not be used." *Id.* at 387–88. When then asked if it is unlawful to make a mistake on the form, the DI testified "[t]he regulation is clear on how to use DEA 222 forms. And [the] DEA 222 form[] states that it should not be filled." *Id.* at 388.

On cross-examination regarding the audit, Respondent's counsel asked the DI if there were any spreadsheets that showed how the DEA 222s were counted and how the dispensings were counted. Tr. 393. The DI answered: "No, I don't have that at this time, sir." *Id.* Then asked whether he had ever had such documents "at any time," the DI answered: "I do not recall at this time if I have this or not." *Id.*

Respondent's counsel then represented that when DEA provided Respondent with the CDs (which contained the records obtained from them) after the Order to Show Cause was served, the CDs included "some scratch papers." Tr. 393. Counsel then asked the DI if he "recall[ed] working out some scratch papers where you may have done the math?" *Id.* at 393–94. Counsel also advised the ALJ that he had copies if it would refresh the DI's recollection. *Id.* at 394. After the DI answered that he did "not recall this," Respondent's counsel asked the DI if it would "refresh [his] recollection if [he] looked at the notes?" *Id.* The ALJ then intervened, stating: "Documentation, even if it does, this documentation is not going to be allowed." *Id.* When Respondent's Counsel then argued that "it's just for impeachment," the ALJ explained that while Respondent's Counsel could impeach the witness, he could not use documents which he did not provide "ahead of time" and that he had "an obligation to provide [the documents] as part of the response to the Pre-hearing Statement." *Id.* at 394–95.

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[38] Contrary to the question, Mr. Parrado had earlier identified the dosage as a red flag. Tr. 304.

[39] Asked whether he had any knowledge as to whether Superior I's computer records were electronically copied, the DI testified that while he did not handle that, he believed that digital evidence was collected. Tr. 372.

[40] The DI subsequently explained he used the inventory which must be taken every two years (*i.e.*, the biennial), "which is required . . . per regulation 1304.11." Tr. 374.

[41] The audit also found an overage of 159 du of morphine sulfate 60 mg ER. GX 4 (No. 15–6).

Respondent's counsel then asserted that the documents were "not intended to be used as an exhibit" but "merely to check the math." *Id.* at 395. He further asserted that when he went "through the DEA 222s on the [m]orphine [s]ulphate tabs and add them up, all the ones that were were returned . . . by the Government, I get to a number of 7,200. And what I'm trying to figure out is whether or not there are any supporting documents where we can see your math to see if you got it correct." *Id.* After the Government objected that Respondent's counsel was testifying and the ALJ expressed his agreement with the Government, Respondents' counsel stated that he wanted to present the 222s to the DI and "walk through the math together and see if Your Honor comes to the same number that they [sic] do." *Id.* at 396. The ALJ ruled that because Respondent's counsel "didn't [timely] present the 222s as evidence," he would not allow the question. *Id.*

Then asked whether he did his calculations "by hand" or by creating a spreadsheet, the DI testified that he could not recall what procedure he used because he did the audit two years earlier. *Id.* at 396–97. Asked if he used only the hard copy 222s or also used the electronic order records, the DI testified that he "used all the DEA 222s that were there[] and there were some CSOS" (electronic orders) as well. *Id.* at 397. The DI subsequently explained that the electronic orders were printed out and that he used the paper copy of these. *Id.* at 401. Then asked whether he did anything to control for math errors, the DI testified that he "reviewed [his] counts on many occasions" and "did some cross checks" with "other documents provided by the pharmacy." *Id.* at 402. The DI also testified that he cross-checked Respondent's purchases by using ARCOS data,[42] but because some distributors report only every quarter, he could only check approximately 95 percent of the purchase data. *Id.* at 402–04.

The Government called another DI, who testified regarding the execution of the AIW at Superior II and the subsequent audit of its handling of controlled substances. *Id.* at 469, 471. The DI testified that she delivered the warrant to the pharmacy manager and did a closing inventory. *Id.* at 471. She then asked for the purchasing records and the hard copy controlled substance prescriptions. *Id.* at 472. The DI testified that she was familiar with patient profiles and that no patient profiles were obtained during the execution of the warrant. *Id.* at 473.

The Government then asked the DI about a number of Superior II's schedule II order forms. *Id.* at 473–74. Regarding the orders forms in GX 6 (No. 15–07), the DI testified that the forms were not filled out properly, as "[t]hey are missing the number of packages received and date received on some of the lines on each form." *Id.* at 474. With respect to the first form in the exhibit, which had two line entries, each for 12 packages of 100 count of oxycodone 30, she identified line two as not being properly completed, apparently because it did not list the number of packages received and the date received. *Id.*

Turning to the second form, she also identified the second line of the form as not being properly completed, apparently because it did not list the number of packages received and the date received. *Id.* However, the first two forms have the same serial number, thus establishing that one of them is a duplicate. *Compare* GX 6, at 1, *with id.* at 2.

As for the next four forms, the DI testified that each was a copy and not the original and was thus a violation. Tr. 474–75; *see also id.* at 521. With respect to several of the remaining forms in the exhibit, she identified that for several of the line items there was no notation that "no packages [were] received or date received." *Id.* at 475; *see also id.* at 476.

However, on cross-examination, the DI testified that she relied on the entries on the forms maintained by Respondent and did not verify whether every line on the 222s had been actually shipped by the distributors. *Id.* at 518. While the DI acknowledged that sometimes distributors don't ship an entire order at once, she then testified that "after 60 days, the 222 is invalid" and the purchaser "should go back and put a zero and the date they put the zero" on the form. *Id.* at 520. However, when asked where, in the *Pharmacist's Manual,* it instructs registrants to do this, the DI answered: "I couldn't tell you which page. But it does say they have to complete the 222 forms." *Id.* When then asked where in the regulation it says that, the DI stated that she did not "know the specific quotation." *Id.*

Moving back to the audit, the DI testified that "we asked for purchasing records[43] and dispensing records, and that the hardcopy original prescriptions[44] were used as the dispensing record." *Id.* at 477. As the starting point of the audit, the DI testified that she "asked when their last physical count was. And we used the July 31st, 2012. And the pharmacist got the numbers from their perpetual inventory." *Id.* On cross-examination, the DI reiterated her earlier testimony that she "did not ask for perpetual inventory numbers. I asked for an actual physical count of those seven drugs." *Id.* at 491. She then explained that Superior II's employees "told me that they take physical counts very frequently" and that she "asked them when their most recent one was that was at least six months" old, "[a]nd these were the numbers I was given." *Id.* at 491–92. As for the closing inventory, the DI testified that the pharmacist "counted the pills, and I witnessed." *Id.* at 477.

According to the DI, the audit found that Superior II was short 40 du of hydromorphone 4 mg and had an overage of 2,576 du of hydromorphone 8 mg. *Id.* at 479. As for the other drugs, the audit found overages of 1,189 du of oxycodone 30 mg, 896 du of methadone 10 mg, 674 du of morphine sulfate 30 mg, 563 du of morphine sulfate 60 mg, and 426 du of morphine sulfate 100 mg. GX 12. According to the DI, "[a]n overage indicates that all records either were not maintained or not provided." Tr. 480.[45]

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[42] *See* 21 CFR 1304.33 (setting forth ARCOS reporting obligations imposed on manufacturers and distributors).

[43] On cross-examination, the DI testified that she used both the paper and electronic 222 forms in doing the audit. Tr. 504. She also testified that "[w]e always ask if there's been any theft or loss, returns, or if they have any outdated drugs." *Id.* She then testified that she specifically recalled asking a pharmacist for these records. *Id.* at 505.

[44] The DI testified that she asked for the hard copy Schedule II prescriptions for the period of January 1, 2011 through October 31, 2011, and from December 1, 2012 to the date of the warrant, February 4, 2013. Tr. 515. She also testified that "I asked for specific date ranges, because there had been a notice of inspection prior to the admin. inspection warrant. So I asked for different date ranges." *Id.* at 514. The DI then explained that she did not participate in the prior inspection. *Id.*

On cross-examination, the DI testified that she did not do any interviews and was not present during any interviews. *Id.* at 485. She further testified that she did not notify Superior II of the audit results and did not know whether another DI had done so. *Id.* at 486. She also testified that she did not do any further investigation into Superior II other than to review the records that were obtained and to complete the audit. *Id.* at 487.

On further cross, the DI testified that in performing the audit, she did not compare the 222 forms she obtained from Superior II with those its suppliers provided to the Agency.[46] *Id.* at 501. She also testified that she could not recall if she obtained ARCOS data to verify whether the documents obtained pursuant to the warrant contained "accurate information," explaining that "[w]hen we conduct [an] audit, it is the registrant's responsibility to provide all documents." *Id.* at 502. Subsequently, the lead investigator on the matter testified that she did not instruct anyone working on the investigation to "consult ARCOS" or to look at either the paper or electronic 222 forms that had been sent to the Agency.[47] *Id.* at 583.

The DI further testified that she kept track of the serial numbers on the 222s by spreading them out on a desk but did not "make a document." *Id.* at 505. Respondent's counsel then asked her if she had considered several orders which he identified by drug, quantity, date, and the order form number. *Id.* The DI responded to these questions stating that if the record was provided, it was considered. *Id.* at 505–08.

Subsequently, the DI acknowledged that pharmacy personnel filling a prescription could make an error when counting the pills. *Id.* at 512. She then identified another DI who was involved in calculating the dispensing totals for the audit, as well as the pharmacy's receipts. *Id.* at 513.

The Government's final witness was a DI from the Tampa office with 19 years of experience as such, who was the lead investigator in the Superior II matter. *Id.* at 539–40; 558. She testified that on November 30, 2012, she participated in a Notice of Inspection at Superior II, which she explained involved "go[ing] on-site and advis[ing] the registrant that we're going to be doing an audit of their controlled substance records." *Id.* at 541. She further testified that during the Notice of Inspection issued to Superior II, "[w]e obtained records, purchase records, and dispensing records which consisted of the prescriptions." *Id.*

The DI testified that she was not present at Superior II when the AIW was executed. *Id.* at 542. However, she did review the records seized from Superior II to include its purchases and dispensing records. *Id.* at 543. She also testified that no patient profiles were taken during the November 30 inspection and that when she reviewed the records obtained from Superior II pursuant to the AIW, she did not see any patient profiles. *Id.* at 544. Subsequently, she testified that the records she told Mr. Parrado that he could not review were the records she obtained from the State's Prescription Drug Monitoring Program. *Id.* at 546–48. And later, on cross-examination, she clarified that Mr. Parrado did not get the PDMP records. *Id.* at 559. She also testified that she did not provide the "partial medical records" to Mr. Parrado, *id.* at 577, and that the records were provided by Government Counsel.[48] *Id.* at 578.

Thereafter, the DI acknowledged that various notations made on the Superior II order forms were her initials and that she did not keep a clean copy of the documents. *Id.* at 549. According to the DI, when she reviews records, she "will usually initial it in some way or the other just to let me know that I did review that record." *Id.* She testified that the 222s that were returned to Respondent had her initials on them. *Id.* at 550.

Turning to Superior's II ordering of controlled substances using the Controlled Substances Order System (CSOS), the DI testified that during the November 30, 2012 inspection, she met with a pharmacist (Mr. Majed) and asked to see its primary records for the receipt of controlled substances. *Id.* at 551. According to the DI, Mr. Majed stated "that once he gets the orders he inputs it into the system[,] . . . places the order[,] . . . then . . . prints out" the form, and upon receipt of "the product, he jots it down where it says packages shipped and packages and dates shipped. So I said this is your receipt. After you receive them manually," at which point Respondent objected.[49] *Id.* at 551–52. After the ALJ overruled the objection, the DI testified that when she asked Mr. Majed what he did once he received product, Mr. Majed said that "he notates [the receipt of product] on this paper form" and that he did not go back into the CSOS and enter the receipt because "he wasn't aware that he had to do that." *Id.* at 554. She then asked Mr. Majed if the paper records were the "primary records" and was told "yes." The DI then testified that these were the records she used for the audit. *Id.*

Continuing, the Government asked the DI whether a printout of an electronic 222 form complied with DEA regulations. *Id.* at 555. According to the DI, the document "should have been linked" and was the "supplier's copy" and not the "purchaser's copy." *Id.* at 556. The DI further explained that "[y]ou see where it says packages shipped? He's not the supplier. He's the purchaser. So that should be packages received and date received. What he's showing me here is the supplier's copy." *Id.* Moreover, to the DI's knowledge, this record was not included in any database. *Id.*

The DI further explained that in order for a person to use the CSOS, the person has to have a pass key. *Id.* at 556–57. However, while Mr. Majed represented that he had a key, the DI subsequently determined that he did not, and that only Mr. Obi (the owner) and another pharmacist (Ms. Minozzi) had pass keys. *Id.* at 557–58.

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[45] Respondent objected to the admission of the computation chart, arguing that the opening inventory was based on Superior II's perpetual inventory, which it is not lawfully required to maintain. Tr. 483. The ALJ overruled the objection. *Id.* While there is no requirement to maintain a perpetual inventory, there is no requirement that the Government use only an actual hand counted inventory in establishing the quantities on hand on the beginning date of the audit period. Indeed, at times, a pharmacy is entirely missing the required inventory and the DIs use zero as the opening inventory.

Most significantly, Respondent ignores that the DI testified multiple times that she asked for an actual physical count which was at least six months old and used what Superior II gave her.

[46] Pursuant to 21 CFR 1305.13(d), "[t]he supplier must retain Copy 1 of the DEA Form 222 for [its] files and forward Copy 2 to the Special Agent in Charge . . . in the area in which the supplier is located."

[47] The evidence also showed that only the DI and the lead DI "handled the prescription records and the 222s." *Id.* at 584.

[48] Later, on re-direct, the Government asked the DI if she had "ever subpoenaed any medical records from any clinics owned by Mr. Obi-Anaduime?" Tr. 589–90. The DI testified that "[o]n the same day of the administrative inspection warrant, we issued subpoenas for the clinic, 21st [sic] Century." *Id.*

[49] Respondent objected on the grounds of hearsay and the lack of notice. As for the latter objection, this was based on the Government having been "aware of [Mr. Majed's] participation in this and [it] gave us no notice in [its] pre-hearing statement that [it] intended to have this witness testify about things that he said." Tr. 552. Respondent did, however, have notice of the issue through the Government's disclosure of the DI's testimony. ALJ Ex. 6, at 6–7 (No. 15–7) ("She will testify that Respondent, as a purchaser of controlled substances *via* [the CSOS], failed to create an accurate record of the quantity of controlled substances received and the date received. She will testify that Respondent failed to electronically archive and link these records to the original order, as required by the . . . [r]egulations."). As for Respondent's objection that the testimony was hearsay, hearsay is admissible in these proceedings and Respondent made no argument as to why the testimony was unreliable.

On cross-examination, the DI acknowledged that because she had the PDMP records she could determine whether the patients were opioid tolerant or opioid naïve. *Id.* at 559–60. The DI did not, however, use that information. *Id.* at 560.

The DI further testified that electronic 222 forms found in Government Exhibit 7 were obtained during the AIW, when she was not present. *Id.* at 563. When then asked whether her testimony regarding the statements made by Mr. Majed were based on her personal knowledge, the DI testified that they were made during the notice of inspection. *Id.*

The DI also testified that Mr. Majed told her that the handwritten notations on printouts of the electronic 222 forms were of the packages that the pharmacy had actually received and the date received. *Id.* at 567. The DI testified that if Superior II pharmacists had correctly documented their receipts of drugs, "they would have printed out the receipt and the receipt date" on a different form and not used the supplier's copy. *Id.* The DI then testified that the receipt record must be electronically linked to the same record that the pharmacy used to place the order. *Id.* at 569.

Respondent's counsel further attempted to ask the DI if she had investigated if Superior II had stopped ordering oxycodone after the AIW. *Id.* at 574. While the Government objected that the question was outside the scope, the ALJ initially overruled the objection. *Id.* However, after Respondent re-asked the question with only an immaterial change in wording, the ALJ barred the question, on the ground that Respondent had not acknowledged any misconduct in its Pre-hearing Statement. *Id.* at 575–77.

Before the Government rested, it requested a ruling from the ALJ clarifying whether Respondents would be allowed to call any witnesses. *Id.* at 594. After the ALJ stated that he agreed with the Government's understanding that Respondents would not be allowed to call any witnesses, Superior II's counsel stated that he intended to call a witness. *Id.*

Asked by the ALJ to provide "the legal basis for . . . Superior II to produce any witnesses, given [his] prior orders," Superior II's counsel stated that "we have noticed witnesses in the Pre-hearing Statement," including Mr. Obi-Anadiume. *Id.* at 595. Again asked to explain the legal basis for calling any witnesses, Superior II's counsel argued that in its Prehearing Statement, it notified the Government that it intended to call "any and all witnesses identified in the Government's Pre-hearing Statement." *Id.* at 597. As to the issues that Mr. Obi would testify to, Superior II's counsel argued that "the summary of [his] testimony" was "covered sufficiently" by the Government in its Prehearing Statement and that "the Government has no prejudice with respect to this." *Id.* at 597–98. Superior II's counsel then asserted that because Government counsel had represented in its Prehearing Statement that it intended to call Mr. Obi and had subpoenaed him, he should be allowed to testify. *Id.* Superior II's counsel further argued that under section 555 of the Administrative Procedure Act, Mr. Obi was an interested person who had the right to participate in the proceeding, and that "fundamental fairness" required that he be allowed to testify. *Id.* at 598–602.

After Superior II's counsel represented that he was making the same motion with respect to Superior I, the ALJ asked if he was relying on the Government's Prehearing Statements as his proffer. *Id.* at 604. Superior II's counsel advised that there was one additional matter that went beyond the scope of the proposed testimony—"the acceptance of responsibility and corrective action." *Id.* at 604. Superior II's counsel further represented that he had "submitted written information to [Government Counsel] with language of proposed acceptance of responsibility and with specific corrective actions that have already been taken, and those that are being taken and those that will be taken in the future." *Id.* at 605.

The ALJ denied the motion, noting that the proffer "clearly . . . exceed[ed] what the Government presented in its Pre-hearing Statement." *Id.* at 606. Continuing, the ALJ stated:

> With all due respect to your colleagues, I think these were well informed lawyers making strategic decisions to keep as little information in the Pre-hearing Statements as possible. And I think it ill-served the course of justice and makes this proceeding a much more difficult process merely because of a strategic decision to keep me in the dark.
>
> I'm not attributing that to you at all. And I don't expect a response, nor will I care to hear a response with respect to that. I've already given Mr. Sisco the opportunity to explain why the record is as it is in documents that I've received from Respondents.
>
> And that record will stand, I will address that at another time in another forum. But from what you've told me, I don't see a legal justification for allowing the Respondent to, in either case . . . present testimony.

Id.[50] The ALJ thus denied Respondents' motion. *Id.* at 606–07.

Superior II's counsel then sought to allow Mr. Obi to testify by asking and "answering the questions [himself] that are posed in the Government's Pre-hearing Statement." *Id.* at 608. The ALJ denied the request. *Id.* Superior II's counsel then sought to take an interlocutory appeal of the ALJ's ruling. *Id.* The ALJ denied the motion. *Id.*

Explaining that he wanted to understand how the proffer would be done, Superior II's counsel then asked the ALJ if he wished for him "to proffer what would be said" by Mr. Obi. *Id.* at 609. The ALJ responded "no," and explained that Superior II's counsel had given him the "substance of what that information would be." *Id.* Superior II's counsel then argued that he should be allowed "to put the full proffer . . . on the record." *Id.*

In response, the ALJ stated that Superior II's counsel had made "a sufficient proffer," noting that he had sought to go "beyond the scope of what the Government covered and enter[] into the area of acknowledgment and remediation [which] would not be permitted[,] [b]ecause you did not disclose it in advance." *Id.* at 610. The ALJ then stated that this told him "the broad parameters" and that was all he needed "to preserve your client's right." *Id.*

Superior II's counsel then explained that his "statements about the Government's Pre-hearing statement and the broader subject matters [was] not the proffer [and] that the proffer is substantially broader [as] it addresses individual patients, because the Government's Pre-hearing Statement called for those things." *Id.* at 610–11. Superior II's counsel then explained that he understood "that this may be a bifurcated issue where there's a notice issue on acceptance of responsibility [and] corrective action," but "no notice issue on what's in the Government's Pre-hearing statement but [was] still being excluded from the record." *Id.* at 611. Superior II's counsel then represented that with respect to "the matter of what is in the Government's Pre-hearing Statement . . . Respondent has an extensive proffer about that for the record which would address a wide variety of things." *Id.* Continuing, Superior II's counsel explained that his previous statements were his "legal argument rather than the factual proffer" and then asked that he "be permitted to actually make the detailed proffer." *Id.* at 611–12.

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[50] While the ALJ then offered the Government the opportunity to respond to the motion, the Government chose not to. Tr. 607.

The ALJ rejected the request, explaining that "[y]ou were permitted to do so. That's what the Pre-hearing Statement was for." *Id.* at 612. Continuing, the ALJ explained that the record now reflected Respondent's proffer and "that the detailed proffer that you're describing was appropriate and was not provided to me in a timely fashion. And I believe that was a strategic decision of prior counsel." *Id.*

The Government then rested. *Id.* at 612–13. Thereafter, Superior II's counsel sought to call Mr. Obi. *Id.* at 614. The ALJ denied the request for the reasons he had previously explained.

Discussion

Under the CSA, "[a] registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4). In the case of a retail pharmacy, which is deemed to be a practitioner, *see* id. § 802(21), Congress directed the Attorney General to consider the following factors in making the public interest determination:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing or conducting research with respect to controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

Id.

"[T]hese factors are . . . considered in the disjunctive." *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). It is well settled that I "may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether" to suspend or revoke an existing registration. *Id.; see also MacKay* v. *DEA*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I "need not make explicit findings as to each one." *MacKay*, 664 F.3d at 816 (quoting *Volkman*, 567 F.3d at 222); *see also Hoxie*, 419 F.3d at 482.[51]

Under the Agency's regulation, "[a]t any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to . . . 21 U.S.C. 824(a) . . . are satisfied." 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the Government's evidence in support of its *prima facie* case is confined to factors two and four.[52] For reasons explained below, I find the Government's evidence insufficient to establish that Respondents' pharmacists violated their corresponding responsibility when they dispensed the prescriptions at issue. However, I find that the Government has established by substantial evidence that Respondents have failed to maintain accurate records, as well as other violations, and that it has thus established that Respondents have committed acts which render their registrations "inconsistent with the public interest." 21 U.S.C. 824(a)(4). Because I further find that Respondents did not properly disclose in advance of the proceeding their proposed evidence as to any remedial measures, I conclude that Respondents have not rebutted the Government's *prima facie* showing. I will therefore order that each Respondent's registration be revoked and that any pending application be denied.

Factors Two and Four—The Respondent's Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

The Dispensing Allegations

"Except as authorized by" the CSA, it is "unlawful for any person [to] knowingly or intentionally . . . manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance." 21 U.S.C. 841(a)(1). Under the Act, a pharmacy's registration authorizes it "to dispense," *id.* § 823(f), which "means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner." *Id.* § 802(10).

The CSA's implementing regulations set forth the standard for a lawful controlled substance prescription. 21 CFR 1306.04(a). Under the regulation, "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *Id.* Continuing, the regulation provides that:

> [t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, *but a corresponding responsibility rests with the pharmacist who fills the prescription.* An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person *knowingly filling* such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.[53]

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[51] In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's or applicant's misconduct. *Jayam Krishna-Iyer*, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821. Likewise, findings under a single factor can support the denial of an application.

[52] As to factor one, there is no evidence that the Florida Department of Health has either made a recommendation to the Agency with respect to either Respondent, or taken any disciplinary action against either Respondent. *See* 21 U.S.C. 823(f)(1). However, even assuming that each Respondent currently possesses authority to dispense controlled substances under Florida law and thus meets a prerequisite for maintaining its registration, this finding is not dispositive of the public interest inquiry. *See Mortimer Levin*, 57 FR 8680, 8681 (1992) ("[T]he Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest."). Accordingly, this factor is not dispositive either for, or against, the revocation of each Respondent's registration. *Paul Weir Battershell*, 76 FR 44359, 44366 (2011) (citing *Edmund Chein*, 72 FR 6580, 6590 (2007), *pet. for rev. denied, Chein* v. *DEA*, 533 F.3d 828 (D.C. Cir. 2008)).

As to factor three, I acknowledge that there is no evidence that either of the Respondents, or Mr. Obi-Anadiume, or any of the Respondents' pharmacists, has been convicted of an offense under either federal or Florida law "relating to the manufacture, distribution or dispensing of controlled substances." 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay*, 75 FR 49956, 49973 (2010), *pet. for rev. denied MacKay* v. *DEA*, 664 F.3d 808 (10th Cir. 2011). The Agency has therefore held that "the absence of such a conviction is of considerably less consequence in the public interest inquiry" and is therefore not dispositive. *Id.*

As to factor five, no evidence was offered with respect to it.

[53] As the Supreme Court has explained, "the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales* v. *Oregon*, 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore*, 423 U.S. 122, 135, 143 (1975)).

Id. (emphasis added).

As the Agency has made clear, to prove a violation of the corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp.,* 80 FR 28667, 28669 (2015). Thus, the Government can prove a violation by showing either: (1) That pharmacist filled a prescription notwithstanding his/her actual knowledge that the prescription lacked a legitimate medical purpose; or (2) that the pharmacist was willfully blind (or deliberately ignorant) to the fact that the prescription lacked a legitimate medical purpose. *See id.* at 28671–72. As to establishing that a pharmacist acted with "willful blindness, proof is required that: '(1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact." *Id.* at 28672 (quoting *Global-Tech Appliances, Inc.*, v. *SEB S.A.*, 563 U.S. 754, 769 (2011)).

Here, the Government makes no claim that any of Respondents' pharmacists dispensed the prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, relying primarily on *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195,* 77 FR 62316, 62341 (2012), the Government argues that a pharmacist violates the corresponding responsibility rule when he/she dispenses a controlled substance prescription "in the face of a red flag (*i.e.*[,] a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription) unless he . . . takes steps to resolve the red flag and ensure that the prescription is valid." Gov. Post-Hrng. Br. 16. The Government argues that each Respondent's pharmacists violated this regulation by filling oxycodone prescriptions which presented various "red flags" which were never resolved. Gov. Post-Hrng. Br. 15–18. Noting that its pharmacy expert gave "unrefuted testimony," the Government argues that "[a]ll of the prescriptions discussed by [its Expert] we[re] for highly abused drugs such as oxycodone and hydromorphone" and "contained one or more of" some six "red flags." *Id.* at 17. It further argues that the Expert "testified that no evidence could be found to show the red flags had been resolved prior to dispensing." *Id.*

As proof for its assertion that the red flags were not resolved, the Government points to its Expert's testimony "that, in the practice of pharmacy, a red flag which is resolved must be documented and that the documentation should be placed on the prescription itself." *Id.* It further notes that the prescriptions contained no notations showing that the pharmacists resolved the red flags (with the exception of the address stickers that were placed on the prescriptions). It further contends that "[t]o the extent the Respondents may argue that [their] practice was to place such documentation elsewhere, that argument flies in the face of evidence showing that [the pharmacies] habitually corrected 'mistakes' related to prescriptions on the prescriptions themselves," such as the missing patient addresses and the instance in which a pharmacist marked on the prescription that it had only been partially filled. *Id.*at 17–18.

Here, I assume that the red flags with respect to each prescription or the convergence of red flags—as there were typically multiple red flags associated with each prescription—establishes that the pharmacists "subjectively believed that there was a high probability" that the various prescriptions lacked a legitimate medical purpose.[54] I nonetheless conclude that the Government has failed to put forward sufficient evidence to establish that the pharmacists failed to resolve the various red flags (*i.e.*, that they deliberately failed to avoid learning of the fact that the prescriptions lacked a legitimate medical purpose).

As noted above, as proof that the pharmacists failed to resolve the red flags, the Government relies solely on the absence of such documentation on the prescriptions themselves and the Expert's testimony that it is the custom in pharmacy practice to document the resolution of a red flag on the prescription. Yet as the Expert conceded, no provision of the Controlled Substances Act, DEA regulations, Florida law, or the Florida Board of Pharmacy's regulations requires that a pharmacist document the resolution of red flags on the prescription itself.[55] While it would be reasonable to draw an adverse inference that a pharmacist failed to resolve a red flag (or flags) from the failure to document the resolution in any manner, the Government offered no evidence that the DIs *even asked* the pharmacists at either Respondent if they documented their resolution of red flags, and if so, where they did so.

Here, a regulation of the Florida Board of Pharmacy (then in effect) specifically required that "[a] patient record system . . . be maintained by all pharmacies for patients to whom new or refill prescriptions are dispensed" and that the "system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing." Fla. Admin. Code 64B–16–27.800. This rule also required that the pharmacy maintain "[a] list of all new and refill prescriptions obtained by the patient at the pharmacy . . . during the two years immediately preceding the most recent entry" and include the "prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber." *Id.* The rule further required that the record include the "[p]harmacist['s] comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug." *Id.* And the rule also required that the pharmacist make "a reasonable effort . . . to obtain from the patient . . . and record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs . . . being used by the patient which may relate to prospective drug review." *Id.* Finally, the rule required that "[t]he pharmacist . . . record any related information indicated by a licensed health care practitioner." *Id.*[56]

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[54] All red flags do not have the same hue, and as the Supreme Court's decision in *Global-Tech* makes plain, proof that a pharmacist dispensed a controlled substance prescription without resolving a red flag which only created a "reasonable suspicion" that the prescription lacked a legitimate medical purpose, is not enough to establish that a pharmacist acted with the requisite scienter. However, where there are multiple red flags, none of which alone would establish the requisite scienter, the combination of red flags may well create a subjective belief that there is a high probability that a prescription lacks a legitimate medical purpose.

[55] While it may be customary in the profession to document the resolution of a red flag on the prescription itself, that does not make it improper to document the resolution someplace else. Moreover, while evidence of a custom certainly has probative value, it is not conclusive proof. *See Sorrels* v. *NCL (Bahamas) Ltd.*, 796 F.3d 1275, 1282 (11th Cir. 2015) ("'[E]vidence of custom within a particular industry, group, or organization is admissible as bearing on the standard of care in determining negligence. Compliance or noncompliance with such custom, though *not conclusive on* the issue of negligence, is one of the factors the trier of fact may consider in applying the standard of care.'") (emphasis added) (quoting *Muncie Aviation Corp.* v. *Party Doll Fleet, Inc.*, 519 F.2d 1178, 1180–81 (5th Cir. 1975)); II Wigmore, Evidence, § 379, at 403 (Tillers rev. ed. 1983) (explaining that with respect to evidence of custom or usage of trade, "the question is not whether the offered instances fully prove the custom alleged, but merely whether they are receivable as having probative value").

[56] This rule remains in effect today; however, the rule now requires that the information be

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Of further note, the Board of Pharmacy's rules require that a pharmacist "review the patient record and each new and refill prescription presented for dispensing in order to promote therapeutic appropriateness." Fla Admin Code r. 64B16–27.810. This rule specifically requires that a pharmacist identify such issues as: "[o]ver-utilization," "[t]herapeutic duplication," "[d]rug-drug interactions," "[i]ncorrect drug dosage," and "[c]linical abuse/misuse." *Id.*

On cross-examination, the Expert testified that he asked DEA "for complete profiles on all these patients" but was told to look at only the prescriptions. Tr. 247; *see also id.* at 324–25 (testimony of Expert that he had asked for patient profiles for the Superior II patients and was told not look at them, although it was unclear whether he actually received them). He further acknowledged that a patient profile would show a patient's complete history of the prescriptions filled at the pharmacy during the period for which it was run, as well as whether the patient was opioid naïve or tolerant. *Id.* at 325. While subsequent testimony suggests that the Agency's Investigators did not obtain the patient profiles (at least with respect to Superior II)[57] but only state PMP reports, both the Board's regulation and the Expert's testimony establish that the patient profiles were relevant evidence in assessing whether Respondents' pharmacists had resolved the red flags, whether they contained such proof or not.

The Government nonetheless argues that it had no obligation to produce the patient profiles and that the Respondents' position would force the Government to "search the entire universe for exculpatory evidence." Gov. Mot. to Supplement the Record, Strike Respondent's Untimely Exceptions, . . . Or, In the Alternative, Respond to Exceptions, at 15. It further argues that it is entitled to an adverse inference that Respondents' pharmacists did not resolve the various red flags because such evidence, if it does exist, is "under the complete control of the Respondent" and "not DEA" and Respondent "fail[ed] to produce" it. *Id.* (citing *Int'l Union, UAW* v. *NLRB,* 459 F.2d 1329, 1336 (D.C. Cir. 1972)).

As for the contention that Respondents' position would force the Government to "search the entire universe for exculpatory evidence," it does no such thing. Indeed, the Government ignores that its own Expert sought to review the patient profiles and that the Board of Pharmacy's rules mandate that a pharmacist review the patient's profile as part of the prospective drug use review which is required before filling a prescription. Unexplained by the Government is why it would be improper for pharmacists to document their resolution of a red flag in the patient profile given that the Board's rules required (and still require) that a pharmacist document his/her "comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug," as well as "any related information indicated by a licensed health care practitioner" in that record.

Of further consequence, the Government produced no evidence establishing when the various patients first filled prescriptions at Respondents for the drugs in the prescriptions at issue here. Unexplained by the Government is why, if the red flags associated with a specific patient and prescription had been previously resolved and this was documented in the patient profile, the pharmacists were nonetheless required to document this on subsequent prescriptions.

I also reject the Government's contention that it is entitled to an adverse inference based on the failure of Respondents to produce any evidence showing that they resolved the red flags. Under the adverse inference rule, if a party has evidence within its control that "would in fact strengthen [its] case, [it] can be expected to introduce it even if it is not subpoenaed." *Int'l Union,* 459 F.2d at 1338. Be that as it may, while the patient profiles remained within Respondents' control, *International Union* itself recognizes that "if a party has good reason to believe his opponent has failed to meet [its] burden of proof, [it] may find no need to introduce his strong evidence." *Id.*

Here, the Government has the burden of proof. *See* 21 CFR 1301.44(d) & (e). While it may be that there is nothing in the patient profiles which would have been favorable to Respondents, given that the Government's Expert acknowledged the relevance of these records and the scope of the information required by the Board's rule to be maintained in them, requiring the Government to put forward evidence as to whether the patient profiles show that the various red flags were not resolved, is not fairly described as requiring it "to search the entire universe for exculpatory evidence." To the contrary, obtaining and reviewing patient profiles would seem to be fundamental to conducting an adequate investigation of the dispensing allegations.

As further support for its contention that the absence of documentation on the prescriptions is proof that the red flags were not resolved, the Government points to the evidence showing that where the physicians failed to include the patients' address, the pharmacists placed address stickers on the prescriptions. It also points to a single prescription, which was partially filled, and that the pharmacist documented this on the face of the prescription.

Yet Florida law expressly required (and still requires) that a patient's address "appear on the face of the prescription." Fla. Sta. Ann. § 893.04(c); *see also* 21 CFR 1306.05(a) ("All prescriptions for controlled substances . . . shall bear the full name and address of the patient[.]").[58] As for the partially filled prescription, a DEA regulation requires that the pharmacist "make a notation of the quantity supplied on the face of the written prescription . . . or in the electronic prescription record." 21 CFR 1306.13(a). By contrast, no law or rule requires the documentation of the resolution of a red flag to be placed on the prescription itself. Finally, it bears repeating that there is no evidence in the record that the Investigators even asked Respondents' pharmacists, as a general matter, if they resolved red flags presented by controlled substance

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maintained for a period of four years preceding the most recent entry.

[57] With respect to Superior I, a DI testified that he believed that digital evidence was collected. Tr. 372.

[58] Quoting 21 CFR 1306.05(a), the Government suggests that prescriptions were "[d]ispensed in an [i]mproper manner." Gov. Post-Hrng. Br. 18. The Government then states: "[a]s evidenced [b]y many of the prescriptions themselves for both Superior I and II, prescriptions were repeatedly issued absent a patient address." *Id.* The Government, however, offers no further explanation as to why Respondents violated federal law by filling the prescriptions given that they contain address stickers for the patients.

Of note, the DEA Office of Diversion Control maintains a Web page of "Questions & Answers" pertaining to prescriptions. *See http://www.deadiversion.usdoj.gov/faq/prescriptions.htm.* One of the questions is: "What changes may a pharmacist make to a prescription written for a controlled substance in schedule II?" *Id.* at 2. In its answer, the Office of Diversion Control noted a conflict between its previous policy and a statement made in a 2007 rulemaking entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances;* the answer further explained that the Agency "plans to resolve this matter through a future rulemaking." *Id.* The Answer then advised that "[u]ntil that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber." *Id.* Because the Government has produced no evidence that Florida law, the Board of Pharmacy's regulations, or the Board's policy prohibited the pharmacists from adding the patient's address to the prescriptions, I reject the Government's suggestion.

prescriptions, and if so, how they documented having done so.[59]

Accordingly, I find that the Government's allegations that Respondents' pharmacists violated 21 CFR 1306.04(a) and Fla. Stat. Ann. § 465.016(1)(s)) when they dispensed controlled substance prescriptions without resolving the red flags presented by the prescriptions are not supported by substantial evidence.[60]

The Audits and Recordkeeping Allegations

The evidence nonetheless shows that both Respondents violated the CSA by failing to maintain and/or properly maintain required records. With respect to Superior I, the evidence is particularly egregious, as an audit conducted by Agency Investigators found that the pharmacy had shortages of 15,560 du of oxycodone 30 mg and 11,951 du of hydromorphone 8 mg. In addition, Superior I was short 946 du of hydromorphone 4 mg, 864 du of methadone 10 mg, 474 du of morphine sulfate 100 mg ER, and 447 du of morphine sulfate 30 mg ER. Thus, Superior I was short more than 30,000 du of highly abused controlled substances. And while Superior II had only a small shortage of a single drug, it had substantial overages in several drugs, including 2,576 du of hydromorphone 8 mg and 1,189 du of oxycodone 30 mg.

"Recordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances." *Paul H. Volkman*, 73 FR 30630, 30644 (2008); *see also Fred Samimi*, 79 FR 18698, 18712 (2014) (finding where physician "had shortages totaling more than 40,000 dosage units" of various drugs that his "inability to account for this significant number of dosage units creates a grave risk of diversion," and that "even were there no other proven violations, the audit results alone are sufficient to . . . establish[] that [physician's] registration[] 'would be inconsistent with the public interest'") (citations omitted).

During the hearing, Respondents raised various challenges to the validity of the audits. With respect to the Superior I audit, Respondent's counsel attempted to impeach the DI's result by using a document he described as "scratch paper" which, according to his representation, had been included among the documents returned to Respondents on the CD and which listed the DEA 222 forms for Superior I's morphine sulfate orders; Respondent's counsel further represented that when he added up the orders, he got a number of 7,200 du. Tr. 395.

I need not decide whether the ALJ erred when he barred Superior I's counsel from using this document to impeach the DI, Tr. 394–95, because Respondent did not properly preserve the claim of error. Notably, Respondent's counsel did not seek to submit the document even as a rejected impeachment exhibit, and in its Post-hearing Brief, Respondent did not specifically identify this ruling as being in error. Indeed, while in its Post-hearing Brief, Superior I proposes as a factual finding that it "proffered Exhibits 3 through 9 including invoices and other records that demonstrate errors in the DEA audit which resolve the alleged inventory *overages,*" Resp. Post-Hrng. Br. 9 (emphasis added), with respect to Superior I, the gravamen of the Government's audit allegation was that it had *shortages* of multiple drugs.[61] Moreover, Exhibits 3 through 9, which comprise nearly 1500 pages of assorted documents, and which purportedly include relevant records for each of the audited drugs, are just that—raw documents, with no accompanying explanation or calculations showing why the Government's audit results are in error.[62]

Respondent also questioned the validity of the audits on the ground that while the DIs could have verified their calculations as to the level of Respondents' purchases of the drugs by obtaining data from the Agency's ARCOS database, they "willfully chose to ignore that evidence which would have demonstrated the accuracy of the pharmacies' records with respect to [their] purchases." *Id.* at 20. Contrary to Respondent's understanding, one of the purposes of an audit is to determine *whether the audited party* is maintaining "a complete and accurate record of each [controlled] substance . . . received, sold, delivered, or otherwise disposed of by him." *See* 21 U.S.C. 827(a)(3); *see also id.* at § 827(a)(1) (requiring registrants to "make a complete and accurate record of all stocks . . . on hand" when "first engag[ing] in the . . . dispensing of controlled substances, and every second year thereafter"). Putting aside that Respondents produced no evidence showing discrepancies between the DIs' calculations as to the quantities of the drugs received by them and the distributions as reported by their suppliers to the ARCOS system, the DIs were entitled to rely on the records provided by Respondent in response to the warrant. Given that ARCOS data is compiled from distribution reports submitted by manufacturers and distributors, and Respondents were not required to file reports to ARCOS, *see* 21 CFR 1304.33(c), the DIs had no obligation to cross-check their calculations with ARCOS data.

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[59] The Government also alludes to testimony by its Expert to the effect that he was shown partial medical records for the patients and that he found no evidence in these records "that any conversation had taken place between the prescriber and the Respondents' pharmacist." Gov. Post-Hrng. Br. 17 n.10. None of these records are in evidence, and thus, there is no evidence establishing when the patients first saw the physicians and whether there was any communication between the pharmacists and prescribers at that time. In any event, there is no evidence in the record establishing that a physician has an obligation under the standard of care to document phone calls from a pharmacist questioning his prescription. Accordingly, I place no weight on this testimony.

[60] As found above, on various occasions, the Government elicited testimony from its Expert, over Respondents' objections, to the effect that some of the prescriptions presented red flags that could not be resolved. While the Government made no argument based on this testimony in its Post-hearing Brief, the ALJ made multiple findings that several of the prescriptions presented red flags that could not be resolved. *See* R.D. 80–81 (FoF#s 9, 10). Moreover, in its Response to Respondent's Exceptions, the Government invokes this evidence. *See* Gov. Response to Resp.'s Exceptions, at 14 ("Notwithstanding the fact that Mr. Parrado credibly testified that he discovered red flags which, in his opinion, were unresolvable . . . Respondents are now arguing for a new rule that requires the Government to prove a negative.") (citing Tr. 145–46, 289–90).

While in the Show Cause Orders, the Government made conclusory allegations to the effect that the Respondents' "pharmacists dispensed controlled substances when they knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose," ALJ Ex. 1, at 2 (No. 15–6), which implies that the red flags could not be resolved, the Government never identified a specific prescription in either Show Cause Order or any of its Prehearing Statements that could not be resolved. As explained previously, while the ALJ overruled Respondents' objections, the correct standard is not whether the ALJ wanted to know the answer to the Government's question, Tr. 287, but whether Respondents knew "what conduct was being alleged and ha[d] a fair opportunity to present [their] defense." *Duane* v. *DOD,* 275 F.3d 988, 995 (10th Cir. 2002) (quoting *Facet Enters., Inc.,* v. *NLRB,* 907 F.2d 963, 972 (10th Cir. 1990). *See also Pergament United Sales,* 920 F.2d at 135 ("Notice does not mean a complaint necessarily must state the legal theory upon which the General Counsel intends to proceed. Instead notice must inform the respondent of the acts forming the basis of the complaint."); *see also id.* ("The primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the complaint and fashioning an explanation that refutes the charge of unlawful behavior.").

Because the Government never alleged that any of the prescriptions could not be resolved, and Respondents objected to this line of inquiry, there is no basis for a finding of litigation by consent. Accordingly, I do not consider the testimony that the some of the prescriptions presented unresolvable red flags.

[61] Likewise, even assuming the correctness of Superior I's counsel's representation that when he added up the morphine sulfate orders, he got "a number of 7,200," Tr. 395, he made no proffer as to errors with respect to the audit results for oxycodone 30 mg and hydromorphone 8 mg, which found massive shortages.

[62] It is noted that Respondents attached, as supplements to their untimely filed Exceptions, charts which purport to show audit results for both pharmacies which are dramatically different from those found by the Government. See Resp. Exceptions, at Appendices A & B. Respondents offered no foundation for consideration of the charts, and in any event, the charts are not properly considered as newly discovered evidence.

Furthermore, while throughout the proceeding, Respondents have argued that their due process rights have been violated because the Agency's Lead Investigator "unlawfully retained" records seized pursuant to the Administrative Inspection Warrants for some 611 days, Resp. Post-Hrng. Br. 18, Respondents were provided with the records on or about the same day they were served with the Show Cause Orders, which made specific allegations as to the audits. Thus, Respondents had approximately 80 days from the date they were informed of the allegations to the date on which they were required to file their Prehearing Statements to investigate the allegations pertaining to the audits and prepare a defense.

While Respondents argue that "[t]he first access [they] had to what may or may not be all of the evidence was on the day that DEA served its Order to Show Cause," Resp. Post-Hrng. Br. 19, they did not identify any records that were necessary to complete their audits which were not provided to them when their records were returned.

Respondent Superior II questioned the validity of the audit pertaining to it, on the ground that the DI based her initial inventory figures on a perpetual inventory which Respondent is not lawfully required to maintain. However, the DI testified multiple times that she asked for an actual physical count which was at least six months old and used what Superior II gave her. Tr. 491–92. I thus reject Respondent's challenge to the findings of the audit of Superior II, which establishes that it had overages in several drugs.[63]

I thus find that both pharmacies failed to maintain complete and accurate records as required by 21 U.S.C. 827(a)(1) & (3). While this finding alone supports the conclusion that each pharmacy has committed such acts as to render its continued registration "inconsistent with the public interest," *see* 21 U.S.C. 824(a)(4), the scope of the shortages of oxycodone 30 mg and hydromorphone 8 mg found during the audit of Superior I supports a sanction of revocation. *See Samimi*, 79 FR at 18712.

The Government further alleges that Respondents failed to properly complete various schedule II order forms. More specifically, with respect to Superior I, the Government's evidence included an Order Form for oxycodone 30 on which the National Drug Code was changed. GX 5, at 1 (No. 15–6). However, while the DI testified that "any alteration or any erasure or change of description" should result in the form not being used," the applicable regulation actually states that the order "*must not be filled* if . . . [t]he order shows any alteration, erasure, or change of any description." 21 CFR 1305.15(a) (emphasis added). Thus, the regulation is not fairly read as imposing liability on Superior I for changing the National Drug Code.

The DI also testified that a second order form was not filled out properly, because "information in regard to the number of package[s] receive [sic] . . . was omitted." Tr. 384. However, the Government offered no evidence that any portion of the two orders listed on the form were filled. While DEA's regulation states that "[t]he purchaser must record on Copy 3 of the . . . 222 the number of commercial or bulk containers on each item and the dates on which the containers are received by the purchaser," 21 CFR 1305.13(e), the Government points to no provision which requires, where no portion of a line entry has been filled by the expiration of the 60-day period in which the Order Form is valid, *id.* § 1305.13(b), the purchaser to notate on the form that no portion of that entry was received.[64]

The Government made similar claims with respect to Superior II. For example, it identified the first two pages of GX 6 (No. 15–7) as examples of Order Forms that were not properly completed because the second entry on each form did not list the number of packages received and the date received. Putting aside that these two documents bear the exact same serial number, here again, the Government put forward no evidence that any portion of the order listed in the second line item was filled. While here too, this DI insisted that "after 60 days, the 222 is invalid" and that Respondent "should go back and put a zero and the date they put the zeros" on the form, as explained above, the regulations do not so require. And while the DI also asserted that the *Pharmacist's Manual*—which does not have the force and effect of law anyway—instructs pharmacists to do this, the *Manual* actually states that "[w]hen the items *are received*, the pharmacist must document on the purchaser's copy (copy three) the actual number of packages received and the date received" and nothing more. DEA, *Pharmacist's Manual—An Informational Outline of the Controlled Substances Act* 23 (Rev. ed. 2010).

While the DI further identified other Order Forms in this Exhibit which she alleged were not properly completed, she did not identify a single instance in which a line item had actually been shipped to Respondent and the entry had not been made. Indeed, with respect to the Exhibit, the only violations the DI identified were that the forms were copies and not the original. Tr. 474–75, 521. Under a DEA regulation, "[t]he purchaser must retain Copy 3 of each executed DEA Form 222." 21 CFR 1305.13(a). Standing alone these violations would be of minimal consequence.

The evidence further showed that while Superior II used the electronic Controlled Substances Ordering System to purchase controlled substances, it did not comply with 21 CFR 1305.22(g). Under this provision, "[w]hen a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record *must be electronically linked to the original order and archived.*" 21 CFR 1305.22(g). The evidence shows that Respondent's pharmacists would print out a copy of the electronic order form and by hand, notate in the boxes in which the Supplier is to list the "Packages Shipped" and the "Date Shipped," the number of packages received and the date received. *See generally* GXs 7 & 10; Tr. 551. According to the DI, when she asked Mr. Majed (one of Superior II pharmacists), how he documented the pharmacy's receipt of the drugs, the pharmacist explained that he did not go back into the CSOS because "he wasn't aware that he had to do that." Tr. 554.

The record thus supports the conclusion that Superior II's receipts were not documented electronically and were not linked to the original order. Thus, I conclude Superior II violated 21 CFR 1305.22(g) with respect to the numerous electronic orders it placed.

The DI also testified that Mr. Majed represented that he had a key which is required under the Agency's regulations for placing electronic orders through the CSOS. Tr. 557–58. Under DEA's regulation, a person must "obtain a CSOS digital certificate from the DEA Certification Authority to sign electronic orders for controlled substances." 21 CFR 1311.10. However, a person is eligible to obtain a CSOS digital certificate only if he/she: (1) is the person who "signed the most recent registration application or renewal application," (2) is "a person authorized to sign a registration application," or (3) has been "granted power of attorney by [the] registrant to sign orders for one or more schedules of controlled substances." *Id.* DEA's regulations further provide that "[o]nly the certificate holder may access or use his or her digital certificate and private key," and "[a] certificate holder must ensure that no one else use the private key" and "prevent unauthorized use of that private key." *Id.* § 1311.30. According to the DI, after her conversation with Mr. Majed, she determined that only Mr. Obi, Respondent's owner, and Ms. Minozzi, another pharmacist, had been issued CSOS keys. Accordingly, I conclude that Respondent violated 21 CFR 1311.30(a) and (c).

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[63] While Superior II also argues that DEA failed to consider ARCOS data in auditing it, I reject the argument for the same reasons that I rejected the argument with respect to Superior I's.

[64] While the purchaser's copy 3 of the form includes columns "To Be Filled In By Purchaser" in which the purchaser lists the "No. of Packages Received" and the "Date Received" for each line item, *see* GX 5 (No. 15–6), if no packages of that item have been received, then there is no date on which they were received.

Accordingly, I conclude that the evidence with respect to factor four—Respondents' compliance with applicable laws related to controlled substances—establishes that each Respondent "has committed such acts as would render [its] registration . . . inconsistent with the public interest." 21 U.S.C. 824(a)(4).

Sanction

Under Agency precedent, where, as here, "the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must ' "present sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility carried by such a registration." ' " *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988))). "Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct." *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Prince George Daniels,* 60 FR 62884, 62887 (1995). *See also Hoxie* v. *DEA,* 419 F.3d at 483 ("admitting fault" is "properly consider[ed]" by DEA to be an "important factor[ ]" in the public interest determination).

While a registrant must accept responsibility and demonstrate that it will not engage in future misconduct in order to establish that its continued registration is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. *See, e.g., Joseph Gaudio,* 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011) (explaining that a respondent can "argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation"); *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Paul Weir Battershell,* 76 FR 44359, 44369 (2011) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and "manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant"); *Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009).

The Agency has also held that " '[n]either *Jackson,* nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be [suspended or] revoked.' " *Gaudio,* 74 FR at 10094 (quoting *Southwood,* 72 FR at 36504); *see also Robert Raymond Reppy,* 76 FR 61154, 61158 (2011); *Michael S. Moore,* 76 FR 45867, 45868 (2011). This is so, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36503). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoptions of "deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions").

Here, the record contains no evidence that the principals of either Respondent acknowledge its misconduct. So too, the record contains no evidence that either Respondent has undertaken any remedial measures.

Respondents attribute this to the ALJ's ruling barring Mr. Obi (Respondents' owner) from testifying. They argue that the ALJ's ruling denied them their right to due process and a fair hearing under the Administrative Procedure Act. *See* Resp. Post-Hrng. Br. 23 (citing, *inter alia, Oshodi* v. *Holder,* 729 F.3d 883, 889 (9th Cir. 2013) (en banc); *Block* v. *SEC,* 50 F.3d 1078, 1085 (D.C. Cir. 1995); 21 [sic] U.S.C. 556). Tallying up the number of each party's objections which the ALJ overruled versus those he sustained, as well as the number of times the ALJ, *sua sponte,* instructed a witness not to answer a question, they assert that "[t]his unmistakable pattern reflects the [ALJ's] clear bias against Respondents." *Id.* at 27. As additional grounds for their contention that the ALJ was biased, they assert that he "refused to require the DEA to obey the order of the Federal Magistrate Judge." *Id.* at 34.

As for their claim of bias, none of their assertions establish bias. As found above, while several of the ALJ's rulings on objections were erroneous, many of them were not, and some of Respondents' objections were clearly lacking in merit. In any event, "judicial rulings alone almost never constitute a valid basis for a bias or partiality motion." *Liteky* v. *United States,* 510 U.S. 540, 555–56 (1994) (citing *United States* v. *Grinnell Corp.,* 384 U.S. 563, 583 (1966)).

As for the contention that bias is established by the ALJ's refusal to require the DI to obey the Federal Magistrate Judge's order, Respondents point to no provision of law which grants an Administrative Law Judge authority to order the Government to comply with an order of a Federal Magistrate Judge.[65] A Magistrate Judge has authority to ensure compliance with his orders, including the power to hold a disobeying party in contempt. *See* 28 U.S.C. 636. Respondents offer no explanation for why they did not seek an order compelling the return of the documents from the Magistrate Judge who approved the warrant. I thus reject Respondents' claim that the ALJ's ruling on Mr. Obi's testimony should be rejected on the ground of bias.[66] Indeed, Respondents self-refute their claim of bias when they argue that "[*t*]*he real reason* that the ALJ refused to let Mr. Obi testify was because he felt like Respondents' counsel had not adequately complied with the disclosure requirements of the ALJ's prehearing order." Resp. Exceptions, at 24 (emphasis added).

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[65] Respondents do not identify what orders the DI violated. If Respondents mean the administrative inspection warrants, the language of the warrants only provided for a return of the warrant to the court and an accounting of the property seized. Resp.'s Post-Hrng. Br., at Attachments 1 and 2. The warrants contained no provision requiring the return of the seized property, and Respondents point to no further orders by the court to return the records.

[66] Respondents further assert that the ALJ's "general bias . . . finds its roots in" what they characterize as "the Administrator's public scolding of the ALJ in *Clair L. Pettinger, M.D.,* 78 [FR] 61591 (2013), for requiring the DEA to follow the procedural rules of the Agency and for his interpretation of the law." *Id.* at 35. Not only is Respondents' explanation of *Pettinger* counterfactual (both the pleading burden imposed by the ALJ and his interpretation of factor two were inconsistent with agency precedent), they cite no authority for their theory. Beyond that, Respondents ignore the extensive protections provided to ALJs under federal law to ensure decisional independence, including that they are not subject to performance appraisals, 5 U.S.C. 4301(2)(D), their pay is set by OPM independent of any evaluation by the Agency, *id.* § 5372, and they are subject to discipline only upon a showing of good cause by the MSPB. *Id.* § 3105.

Respondents thus assert that the ALJ erred in barring Mr. Obi from testifying because he was an interested person within the meaning of the APA. That Mr. Obi is an interested person is hardly disputable. However, while an interested person has a right to participate in a proceeding, that right is subject to the reasonable procedural rules of the Agency and rulings of the ALJ. *See, e.g.,* 5 U.S.C. 556(c) ("Subject to published rules of the agency and within its powers, employees presiding at hearings may . . . regulate the course of the hearing."); 21 CFR 1316.58(a) ("The presiding officer may direct that summaries of the direct testimony of witnesses be prepared in writing and served on all parties in advance of the hearing.").

Here, in his Orders for Prehearing Statements, which were issued more than one month before Respondents' Prehearing Statements were due, the ALJ specifically warned Respondents that if their "corporate representative intends to testify, the representative must be listed as a witness, and a summary of anticipated testimony as described below must be provided." ALJ Ex. 5, at 2 (No. 15–6); ALJ Ex. 6, at 2 (No. 15–7). The Orders for Prehearing Statements also cautioned Respondents that their summaries of testimony must "indicate clearly each and every matter as to which Respondent[s] intend[ ] to introduce evidence in opposition" and that "[t]he summaries are to state what the testimony will be rather than merely listing the areas to be covered." ALJ Ex. 5, at 2 (No. 15–6); ALJ Ex. 6, at 2 (No. 15–7). And finally, the Orders for Prehearing Statements further warned "that testimony not disclosed in the prehearing statements or pursuant to subsequent rulings is likely to be excluded at the hearing." ALJ Ex. 5, at 2 (No. 15–6); ALJ Ex. 6, at 2 (No. 15–7).

Respondents thus had fair notice of the steps they were obligated to take to present Mr. Obi's testimony. While Respondents represented in their Prehearing Statements that they intended to call "[a]ny and all witnesses identified in the Government's Prehearing Statement[s] in th[ese] matter[s]," and the Government identified Mr. Obi as a potential witness therein, Respondents entirely failed to provide a summary of the testimony they intended to elicit from him. ALJ Ex. 9, at 4 (No. 15–6); ALJ Ex. 12, at 4 (No. 15–7).

While at the hearing Respondents asserted that there would be no prejudice to the Government because "the summary of Mr. Obi's testimony" was "covered sufficiently" by the Government in its Prehearing Statements, the Government's summary of Mr. Obi's anticipated testimony was confined to questioning him about past acts. Tr. 597–98; *see also* ALJ Ex. 7, at 6–7 (No. 15–6); ALJ Ex. 7, at 8–9 (No. 15–7). Indeed, Respondents' Counsel conceded that he intended to elicit testimony from Mr. Obi as to the corrective actions Respondents had undertaken and that this raised a notice issue. *Id.* at 611. Moreover, at no point prior to the hearing did Respondents provide notice to the Government that *any* of their proposed witnesses would testify regarding any corrective actions undertaken by the pharmacies.[67] *See* ALJ Ex. 9, at 4–6 (No. 15–6); ALJ Ex. 12, at 4–6 (No. 15–7). Thus, the ALJ did not abuse his discretion when he barred Mr. Obi from testifying.[68] *See Gunderson* v. *Department of Labor,* 601 F.3d 1013, 1021 (10th Cir. 2010).

Indeed, in their Post-Hearing Brief, Respondents argue that "Mr. Obi's testimony could have been restricted to the issues discussed in the DEA's prehearing statement." Resp. Post-Hrng. Br. 24. However, as explained above, to rebut the Government's *prima facie* case, Respondents bore the burden of producing evidence as to their remedial measures. Thus, even if Mr. Obi had testified to those issues identified in the Government's Prehearing Statements and acknowledged Respondents' misconduct (as to those violations proven on the record), Respondents still would have failed to rebut the Government's *prima facie* case. Accordingly, even if it was error to bar Mr. Obi's testimony as to the issues discussed in the Government's Prehearing Statements, Respondents have not shown prejudice. *See Gunderson,* 601 F.3d at 1021 (An ALJ's error in excluding evidence must " 'prejudicially affect a substantial right of a party' "; "[a]n error is prejudicial only 'if it can be reasonably concluded that with . . . such evidence, there would have been a contrary result.'") (quoting *Sanjuan* v. *IBP, Inc.,* 160 F.3d 1291, 1296 (10th Cir. 1998)); *see also Air Canada* v. *Department of Trans.,* 148 F.3d 1142, 1156 (D.C. Cir. 1998) ("As incorporated into the APA, the harmless error rule requires the party asserting error to demonstrate prejudice from the error.") (citing 5 U.S.C. 706). I thus reject Respondents' contentions with respect to the ALJ's ruling which barred Mr. Obi's testimony.[69]

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[67] Respondents' reliance on *Oshodi* is not persuasive. Therein, the Ninth Circuit overturned a decision of the Board of Immigration Appeals (BIA), which affirmed a decision of an Immigration Judge that Oshodi, who was an applicant for asylum, was not credible. 729 F.3d at 885. Specifically, the court held that the Immigration Judge violated the applicant's right to due process "by cutting off his testimony on the event of his alleged past persecution . . . that [were] the foundation of his" claims, and denied his claims "solely on the basis of [an] adverse credibility finding." *Id.*

Respondents also cite to *Kerciku* v. *INS,* 314 F.3d 913 (7th Cir. 2003), asserting that the ALJ violated their rights to due process by precluding them from putting on any case. Resp. Post-Hrng. Br. 2. In *Kericku,* the Seventh Circuit vacated a BIA decision which upheld an IJ's denial of applications for asylum, faulting the IJ for not allowing the applicants "to make any presentation." 314 F.3d at 918.

Neither case, however, raised the issue of whether a party could be barred from putting on testimony when the party entirely failed to comply with an agency rule which requires disclosure of the substance of that testimony in advance of the proceeding to prevent prejudice. While Respondents also argue that the ALJ did not neutrally apply this rule, I have carefully reviewed the parties' respective Prehearing Statements, and conclude otherwise.

[68] In *Hatem M. Ataya, M.D.,* 81 FR 8221, 8243 (2016), I held that while the Agency's case law requires a respondent to acknowledge its misconduct and put on evidence of its remedial measures to rebut the Government's *prima facie* case, the Agency's cases do not require a respondent "to admit to the allegations even before [it] even has the opportunity to challenge the Government's evidence." Thus, in *Attaya,* I held that a respondent's failure to acknowledge his misconduct in his prehearing statement could not bar him from introducing evidence of his remedial measures. *Id.* at 8242. However, in *Attaya,* I also held that because the respondent had not adequately disclosed "with sufficient particularity" his evidence of remedial measures, the testimony could nonetheless be barred.

Here, while Respondents failed to set forth any proposed testimony by Mr. Obi on the issue of acceptance of responsibility in advance of the hearing, this would not have been a bar to Mr. Obi's testimony as to Respondents' corrective measures, had such proposed testimony on the latter issue been disclosed in advance of the hearing. Just as in federal court, evidence that a respondent had undertaken remedial measures is not proof that it has engaged in culpable conduct. *Cf.* Fed. R. Evid. R.407.

While a respondent retains the right to challenge the allegations at the proceeding, when the Government serves a party with a show cause order, a respondent should assume that the Government has probable cause to support the allegations and a good faith basis for seeking the action (revocation or suspension) it proposes. A wise respondent conducts its own investigation to determine whether the allegations are true, and if they are, to then determine what measures are needed to correct the violations or offending practices. Thus, while a respondent retains the right to challenge the Government's evidence at the hearing, it is still properly charged with the obligation to disclose the remedial measures it has undertaken as a condition of being able to present such evidence at the hearing. Of course, where the Government fails to prove an allegation at the hearing, a respondent need not put on evidence of any corrective measures relevant to that allegation.

[69] As for Respondents' arguments with respect to the ALJ's ruling which precluded them from submitting their documentary evidence, *see* Resps.' Post-Hrng. Br. at 30–32, the ALJ's Prehearing Orders were clear enough that the documents had to be submitted in hard copy. Moreover, my holding that the Government has failed to prove any of the

Because Respondents failed to produce any evidence of remedial measures undertaken to address the numerous recordkeeping issues that I find proven on the record, I conclude that Respondents have not rebutted the Government's *prima facie* showing they have "committed such acts as [to] render [their] registration[s] inconsistent with the public interest." 21 U.S.C. 824(a)(4). And based on the substantial shortages found at Superior I, which supports the conclusion that it has major recordkeeping issues and/or has engaged in diversion, I conclude that revocation of its registration is warranted to protect the public interest.[70]

I acknowledge that Superior II's recordkeeping violations did not involve large shortages but rather overages. However, the pharmacy nonetheless failed to maintain complete and accurate records as required by the CSA, did not properly document its receipts on electronic order forms, and allowed an unauthorized person to access the electronic ordering system. In addition, the pharmacies have common ownership in that they are both owned by Mr. Obi. Thus, while the conduct proven with respect to Superior I is more egregious than that proved with respect to Superior II, given that Mr. Obi owns and controls each pharmacy, I conclude that revocation is warranted with respect to Superior II as well.[71]

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a)(4) and 823(f), as well as 28 CFR 0.100(b), I order that DEA Certificates of Registration BS9255274 and BS9699731 issued to Superior Pharmacy, L.L.C., be, and they hereby are, revoked. I further order that any application of Superior Pharmacy, L.L.C., to renew or modify either registration, be, and it hereby is, denied. This Order is effective June 17, 2016.

Dated: May 7, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–11550 Filed 5–17–16; 8:45 am]

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dispensing violations renders moot their contentions with respect to those exhibits that were relevant to those allegations.

As for the thousands of pages of exhibits that include records of Respondents' purchases and dispensings of the controlled substances audited by the Government, because Respondents failed to make an adequate proffer as to their audit results prior to the hearing, the ALJ did not abuse his discretion in declining to admit this evidence.

[70] Given the size of the shortages, the Agency's deterrence interests also support revocation.

[71] In numerous cases, DEA has held that where misconduct has previously been proved with respect to the owners, officers, or key employees of a pharmacy, the Agency can deny an application or revoke a registration of a second or subsequent pharmacy where the Government shows that such individuals have influence over the management or control of the second pharmacy. *See, e.g., Lawsons & Sons Pharmacy and Fenwick Pharmacy*, 48 FR 16140, 16141 (1983); *Orlando Wholesale, L.L.C.*, 71 FR 71555, 71557 (2006) (denying application noting evidence that "one of Respondent's managing members had previously operated a business which distributed List I chemicals without a valid registration"); *Cf. 4 OTC, Inc.*, 77 FR 35031, 35035 (2012) (denying application for registration as List I chemical distributor where evidence showed that a person holding a 10 percent interest in applicant had been found by Canadian regulatory agency to have violated its List I regulations).

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Wednesday,
No. 96 May 18, 2016

Part III

Environmental Protection Agency

40 CFR Parts 122, 123, 124, et al.
National Pollutant Discharge Elimination System (NPDES): Applications and Program Updates; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122, 123, 124 and 125

[EPA–HQ–OW–2016–0145; FRL 9936–62–OW]

RIN 2040–AF25

National Pollutant Discharge Elimination System (NPDES): Applications and Program Updates

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes revisions to the National Pollutant Discharge Elimination System regulations to eliminate regulatory and application form inconsistencies; improve permit documentation, transparency and oversight; clarify existing regulations; and remove outdated provisions. This proposal would make specific targeted changes to the existing regulations and would not reopen the regulations for other specific or comprehensive revision. These proposed regulatory changes cover 15 topics in the following major categories: permit applications; the water quality-based permitting process; permit objection, documentation and process efficiencies; the vessels exclusion; and the Clean Water Act (CWA) section 401 certification process. These revisions would further align NPDES regulations with statutory requirements from the 1987 CWA Amendments and more recent case law requirements. By modernizing the NPDES regulations, the proposed revisions would provide NPDES permit writers with improved tools to write well-documented permits to protect human health and the environment. The revisions would also provide the public with enhanced opportunities for public participation in permitting actions.

DATES: Comments must be received on or before July 18, 2016.

ADDRESSES: EPA has set up two Dockets for submitting comments. Submit your comments on the NPDES Application and Updates rule to Docket ID No. EPA–HQ–OW–2016–0145 at *http://www.regulations.gov.* Regarding potential future changes to application forms and information collection requirements, submit your comments to Docket ID No. EPA–HQ–OW–2016–0146 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Erin Flannery-Keith, Water Permits Division, Office of Wastewater Management, Mail Code 4203M, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; (202) 566–0689; *flannery-keith.erin@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA is proposing targeted revisions to the NPDES regulations. These revisions would make the regulations consistent with the 1987 CWA Amendments and with applicable judicial decisions. These revisions would delete certain regulatory provisions that are no longer in effect and clarify the level of documentation that permit writers must provide for permitting decisions. EPA is also asking for public comments on potential ways to enhance public notice and participation in the permitting process. CWA section 402 established the NPDES permitting program and gives EPA authority to write regulations to implement the NPDES program. 33 U.S.C. 1342(a)(1), (2).

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I. General Information

A. Does this action apply to me?

Entities potentially affected by this action are: EPA; authorized state, territorial, and tribal programs; and the regulated community. This table is not intended to be exhaustive; rather, it provides a guide for readers regarding entities that this action is likely to regulate.

TABLE I–1—ENTITIES POTENTIALLY AFFECTED BY THIS PROPOSED RULE

Category	Examples of potentially affected entities
State, Territorial, and Indian Tribal Governments.	States, Territories, and Indian Tribes authorized to administer the NPDES permitting program; States, Territories, and Indian Tribes that provide certification under section 401 of the CWA; States, Territories, and Indian Tribes that own or operate treatment works.
Municipalities	POTWs required to apply for or seek coverage under an NPDES individual or general permit and to perform routine monitoring as a condition of an NPDES permit.
Industry	Facilities required to apply for or seek coverage under an NPDES individual or general permit and to perform routine monitoring as a condition of an NPDES permit.

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What action is EPA taking?

EPA is proposing targeted revisions to the NPDES regulations. These revisions would make the regulations consistent with the 1987 CWA Amendments and with requirements established by judicial decisions. These revisions would delete certain regulatory provisions that are no longer in effect, and clarify the level of documentation that permit writers must provide for permitting decisions. These revisions would also allow permit writers to use more consistent data for permitting decisions and would modernize opportunities for public notice and participation in NPDES permitting actions.

C. What is EPA's authority for taking this action?

CWA section 402 established the NPDES permitting program and gives EPA authority to write regulations to implement the NPDES program. 33 U.S.C. 1342(a)(1), (2).

D. What are the incremental costs and benefits of this action?

This proposal involves several revisions to the NPDES regulations. It is EPA's view that these revisions would generally not result in new or increased workload or information collection by authorized states or the regulated community. The proposed fact sheet documentation requirements may impose only a minimal burden for the permit writer to document permit development analyses that he or she has already conducted. The assessment of impacts is provided for each topic in section IV of this proposal.

II. Background and Executive Summary

The Federal Water Pollution Control Act Amendments of 1972, commonly referred to as the Clean Water Act, were enacted to restore and maintain the chemical, physical, and biological integrity of the nation's waters. CWA section 301 prohibits the discharge of any pollutant to waters of the United States except in compliance with certain sections of the Act, including CWA section 402. Section 402 established the NPDES permit program to be administered by EPA or authorized states, territories or eligible tribes.[1] The NPDES permit program provides two types of permits, individual and general, that may be used to authorize point source discharges of pollutants to waters of the United States. Individual permits are issued by the state or EPA to a single facility and require submission of a permit application. General permits are developed by the state or EPA to cover classes or categories of dischargers under a single permit. General permits typically require facilities seeking permit coverage to submit a notice of intent (NOI) to be covered, the contents of which are described in the general permit. Both types of permits are issued for a fixed period of time not to exceed five years. CWA section 402(b)(1)(B) and 40 CFR 122.46.

Under the NPDES regulations, EPA has developed eight individual permit application forms for applicants seeking coverage under individual permits. 40 CFR 122.21. Each individual permit application form corresponds to a different category of dischargers subject to permitting.[2] After receiving an application for an individual permit, the permit writer reviews the application for completeness and accuracy. Once the permit writer determines that the application is complete, the permit writer uses the application data to develop the draft permit and either the fact sheet or statement of basis that explains the rationale behind the draft permit provisions. 40 CFR 122.21.

The first major step in the permit development process is deriving technology-based effluent limits (TBELs). 40 CFR 122.44(a). The permit writer then determines whether, after application of the TBELs, the discharge will cause, have the reasonable potential to cause, or contribute to an excursion above a narrative or numeric criterion within a state water quality standard (WQS). If the permit writer determines that, notwithstanding application of technology-based limits, the discharge "will cause, have the reasonable potential to cause, or contribute to an excursion above any [s]tate water quality standard," the permit writer derives effluent limitations necessary to meet state WQS (*i.e.,* water quality-based effluent limits (WQBELs)). 40 CFR 122.44(d)(1). The permit writer then includes final effluent limitations (TBELs and WQBELs) that implement all applicable technology and water quality standards in the permit. After developing the effluent limits, the permit writer develops and includes appropriate monitoring and reporting conditions and facility-specific special conditions. 40 CFR 122.43, 122.44(i), 122.44(k) and 122.48. The permit writer also includes the standard conditions that are required for all NPDES permits. 40 CFR 122.41 and 122.42. The permit's fact sheet or statement of basis documents the decision-making process for deriving the permit limits and establishing permit conditions. 40 CFR 124.7, 124.8 and 124.56.

After the draft permit is complete, the permitting authority provides an opportunity for public participation in the permitting process. A public notice announces the availability of the draft permit and administrative record and gives interested parties an opportunity to submit comments and request a public hearing. 40 CFR 124.10 and 124.11. After taking into account all significant comments raised during the comment period, the permitting authority develops the final permit with careful attention to documenting the process and decisions for the administrative record. The permitting authority then issues the final permit to the facility. 40 CFR 124.10, 124.15, and CWA section 402(b).

Under CWA section 402(b), a state or eligible tribe[3] may obtain authorization to administer the NPDES permit program. In order to obtain authorization, the state or eligible tribe must demonstrate to EPA that it has the authorities and resources necessary to implement the program as outlined in CWA section 402(b) and as specified in an EPA/state memorandum of agreement (MOA). When EPA revises the NPDES regulations, authorized states may need to amend their own regulations and legal authorities to ensure their programs continue to be as stringent as the federal program. To date, 46 states and the Virgin Islands have obtained authorization to administer the NPDES permit program.[4] In general, once a state is authorized to administer the program, EPA no longer conducts these activities. CWA section 402(c) and 402(n). However, in accordance with CWA section 402(d), its implementing regulations at 40 CFR 123.44, and the EPA/state MOA, the state must provide EPA with an opportunity to review certain permits, and EPA may object based on one or more of the causes identified in these regulations. If the state permitting agency does not satisfactorily address the points of objection within the applicable timeframe, exclusive authority to issue the permit passes to EPA. 40 CFR 123.44(h)(3).

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[1] Hereafter, the use of "state" includes states and territories unless otherwise noted. Tribes can apply to administer NPDES programs pursuant to 40 CFR 123.32 and 123.33. Because no tribe has yet applied under these sections, this preamble does not specifically discuss tribes. The proposed rule would apply, however, to any tribal NPDES program authorized by EPA in the future.

[2] The current suite of NPDES application forms can be found at *http://www.epa.gov/npdes/npdes-applications-and-forms.*

[3] A tribe found eligible pursuant to § 123.32 to be treated in a manner similar to a state to administer the NPDES program.

[4] Authorized states are listed in *http://www.epa.gov/npdes/npdes-state-program-information.*

If a state or tribe does not have an approved NPDES program, EPA administers the NPDES program. Under CWA section 401, a federal agency may not issue a permit or license for an activity that may result in a discharge to waters of the United States until the state or tribe[5] where the discharge would originate has granted or waived section 401 certification. The central feature of section 401 is the state or tribe's ability to either grant, grant with conditions, deny, or waive certification.

EPA regulations establish permit application requirements and corresponding forms for use by all applicants for EPA-issued permits. Where a state chooses not to use the EPA forms, the state is responsible for developing and using its own forms; however, the state forms must collect all of the data that the EPA regulations require.

EPA has developed several guidance documents to help permitting authorities manage the quality and consistency of NPDES permits. The *NPDES Permit Writers' Manual* (NPDES PWM)[6] provides a comprehensive overview of the framework of the NPDES program and provides basic training on the requirements for the development and issuance of a legally defensible and enforceable NPDES permit. The NPDES PWM is also a resource for other stakeholders interested in the NPDES permitting process.

The revised *Technical Support Document for Water Quality-Based Toxics Control* (TSD)[7] provides states and EPA Regional offices with guidance on procedures for use in the water quality-based control of toxic pollutants. The document provides guidance for each step in the water quality-based toxics control process, from the technical and regulatory considerations for the application of WQS to NPDES compliance monitoring and enforcement.

This proposed rule addresses application, permitting, monitoring, and reporting requirements that have become obsolete or outdated due to programmatic and technical changes that have occurred over the past 35 years. These topics were selected from previous NPDES regulatory streamlining efforts, recommendations from EPA Headquarters and Regional offices, and recommendations from state NPDES permitting agencies. With these proposed revisions and requests for public comment, EPA aims to allow easier determination of who is regulated, clarify applicable compliance requirements, and improve transparency by providing permitting authorities and the public with timely and quality access to information on regulated entities' activities. These revisions would make specific, targeted changes to several sections of the NPDES regulations, and are not intended to reopen the regulations for other revisions.

EPA identified this proposal in response to Executive Order 13563 *Improving Regulation and Regulatory Review* in the document *Improving Our Regulations: Final Plan for Periodic Retrospective Reviews of Existing Regulations* (section 2.1.8). This effort is a "plan, consistent with law and its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives."[8] The issues being addressed in this rulemaking directly align with the goals established in Executive Order 13563.

The proposed rule covers 15 topics grouped into major categories of changes: Permit application requirements; the water quality-based permitting process; permit objection, documentation, and process efficiencies; vessels exclusion; and the CWA section 401 certification process. This is a table of the proposed or discussed changes in those categories.

TABLE II–1—PROPOSED TOPICS FOR REVISION AND PUBLIC COMMENT

Category	Proposed topic for revision
Permit Application Requirements.	• Purpose and Scope (40 CFR 122.1).
	• NPDES Program Definition including: Pesticide Applications to Waters of the United States, Proposed Permit, New Discharger and Whole Effluent Toxicity Definition (40 CFR 122.2);
	• Changes to Existing Application Requirements (40 CFR 122.21).
Water Quality-Based Permitting Process.	• Antidegradation Reference (40 CFR 122.44(d));
	• Dilution Allowances (40 CFR 122.44(d));
	• Reasonable Potential Determinations for New Discharges (40 CFR 122.44(d));
	• Best Management Practices (40 CFR 122.44(k);
	• Anti-backsliding (40 CFR 122.44(l));
	• Design Flow for Publicly Owned Treatment Works (40 CFR 122.45(b)).
Permit Objection, Documentation and Process Efficiencies.	• Objection to Administratively Continued Permits (40 CFR 123.44);
	• Public Notice Requirements (40 CFR 124.10(c));
	• Fact Sheet Requirements (40 CFR 124.56); and
	• Deletion of 40 CFR 125.3(a)(1)(ii).
Vessels Exclusion	• Vessels Exclusion (40 CFR 122.3(a)).
CWA section 401 Certification Process.	• CWA section 401 Certification Process (40 CFR 124.55(b).

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[5] Some tribes have EPA-approved water quality standards. *See* 40 CFR 131.8.

[6] U.S. EPA NPDES Permit Writers' Manual; U.S. EPA, Office of Water, September 2010; EPA–833–K–10–001. (NPDES PWM) *http://www.epa.gov/npdes/pubs/pwm_2010.pdf.*

[7] U.S. EPA Technical Support Document for Water Quality-based Toxics Control, Office of Water, March 1991; EPA–505–2–90–001. *http://www.epa.gov/npdes/pubs/owm0264.pdf.*

[8] Improving Our Regulations: Final Plan for Periodic Retrospective Reviews of Existing Regulations, August 2011, *available at http://www2.epa.gov/sites/production/files/2015-09/documents/eparetroreviewplan-aug2011_0.pdf.*

III. Proposed Revisions

A. Proposed Revisions to Part 122

1. Purpose and Scope (40 CFR 122.1)

(a) NPDES contact information.

EPA is correcting contact information included in the Note to § 122.1 by deleting outdated references to program contact information that is no longer available to "Information concerning the NPDES program and its regulations can be obtained by contacting the Water Permits Division (4203), Office of Wastewater Management, U.S.E.P.A., 1200 Pennsylvania Avenue NW., Washington, DC 20460 and by visiting the homepage at *http://www.epa.gov/npdes.*"

2. NPDES Program Definitions (40 CFR 122.2)

(a) Pesticide Applications to Waters of the United States

EPA proposes to add a definition of "pesticide applications to waters of the United States." In 2009, the decision in *National Cotton Council, et al.* v. *EPA,* 553 F.3d 927 (6th Cir. 2009) found that point source discharges of biological pesticides and chemical pesticides that leave a residue to waters of the United States are pollutants under the CWA and therefore require NPDES permits. EPA, and subsequently authorized states, developed a Pesticide General Permit (PGP) [9] to permit discharges for certain use patterns. EPA finalized its PGP in October 2011.

This proposal defines the term "pesticide applications to waters of the United States" to mean point source discharges to waters of the United States resulting from the application of biological pesticides or chemical pesticides that leave a residue. This definition would clarify who is already regulated by ensuring that the NPDES regulations are consistent with the 6th Circuit decision. By defining "pesticide applications to waters of the United States" in its comprehensive NPDES definitions at 40 CFR 122.2 in the same way as the PGP defines covered activities, EPA would increase clarity and consistency. This definition would not in any way change which pesticide discharges are subject to NPDES permitting.

EPA seeks comments on this proposed definition.

(b) Proposed Permit

EPA proposes to revise the existing definition of "proposed permit." The definition would be expanded to include a state-issued NPDES permit designated as a "proposed permit" under a new section of the regulations, § 123.44(k).

EPA seeks comments on this proposed definition, described below in the discussion of the proposed new § 123.44(k). See preamble section III.B.1, "Objection to Administratively Continued Permits (40 CFR 123.44)."

(c) New Discharger

EPA is correcting a typographical error in subsection (d) of this definition by changing "NDPES" to "NPDES."

(d) Whole Effluent Toxicity (WET)

EPA proposes to revise the existing definition of WET to refer to both acute (lethal) and chronic (lethal and sublethal) WET test endpoints. The current WET definition in § 122.2 states that WET is "the aggregate toxic effect of an effluent measured directly by a toxicity test." The proposed clarified definition would specify that toxicity can include both acute and chronic effects.

This clarification would be consistent with EPA's interpretation of its existing WET regulations, as reflected in the preamble to the NPDES regulations establishing the existing WET definition, and in EPA's WET test methods. In the preamble to the regulations that established this definition, EPA stated, "effluent limitations may be expressed as chronic toxicity or acute toxicity (or both)," recognizing that toxicity can include both endpoints. 54 FR 23871 (June 2, 1989). Similarly, EPA's 2002 promulgated WET freshwater and saltwater test methods include definitions for both acute and chronic (sublethal) toxicity, and procedures for testing for both acute and chronic (sublethal) toxic effects, also demonstrating that WET encompasses both types of toxicity. 40 CFR 136.3; 67 FR 69952, November 19, 2002.[10] In these test methods, EPA defines "acute toxicity" as a short-term observation (24 to 96 hours) including death (lethality). EPA defines "chronic toxicity" as a longer-term observation (1 hour and up to 9 days) for life-cycle endpoints which includes lethality (death) and other sublethal endpoints such as effects on growth, reproduction, and mobility.[11] EPA's WET test methods, including the procedures for both acute and chronic (including sublethal endpoints) toxicity tests, were challenged and subsequently upheld in *Edison Electric Inst. et al.* v. *EPA*. 391 F.3d 1267 (D.C. Cir. 2004).

This proposed clarification would also be consistent with WET program guidance documents [12] and EPA's Great Lakes Initiative. *See* 40 CFR 132.2; Appendix F to Part 132, Procedure 6. These documents include references to and discussion of both acute and chronic toxicity (including sublethal effects such as propagation) and acute and chronic WET test endpoints.

Defining toxicity to include sublethal effects is consistent with the CWA, which establishes a national goal of "water quality which provides for the protection and propagation of fish, shellfish and wildlife." CWA section 101(a)(2). CWA sections 301 and 302 contain various other references to the "protection and propagation" of aquatic organisms, evidencing an intent to protect against not only lethality but also sublethal effects on fish and wildlife. CWA sections 301(h)(2), 301(g)(2)(C), 302(a), 304(a)(5)(B).

EPA notes that this proposed clarification would not change any existing regulatory requirements with respect to inclusion of acute or chronic WET limits in permits. Specifically, it would not change the existing requirement that NPDES permits include WET limits where necessary to meet state numeric and narrative water quality criteria for aquatic life protection. 40 CFR 122.44(d)(1)(iv) and (v). Under this regulation, permit limits must be written to meet states' WET WQS. Thus, if a state's WET WQS require controls for both acute and chronic toxic effects, permit limits must be written to meet both WET test endpoints. If a state's WET WQS require controls only on either acute or chronic toxicity, then the permit WET limits would be written to meet protection of only the applicable WET endpoints.[13] The proposed clarification of the current definition would not change the current regulatory requirements for whether permits must control for acute or chronic toxicity—which is currently, and will continue to be, based on the level of protection against toxicity that the state's WQS provide. The proposed clarification would simply reflect what is already clear under EPA's promulgated WET test methods and other documents referenced above, and in state water quality criteria for WET: That WET can include both acute and chronic (sublethal) effects. Because permit limits would continue to be based on a state's applicable water quality criteria for toxicity, whether acute and/or chronic, the proposed clarification would not change current longstanding practice of implementing WET or increase any burden on permittees.

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[9] U.S. Environmental Protection Agency National Pollutant Discharge Elimination System Pesticide General Permit (PGP) for Discharges from the Application of Pesticides, October 31, 2011. *http://www3.epa.gov/npdes/pubs/final_pgp.pdf.*

[10] 2002 ratified EPA WET Test Methods (Acute and Chronic freshwater and saltwater WET methods such as "Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms [Third Edition/ October 2002]"—see introduction sections 2.1.1 and 2.1.2). See *http://www.epa.gov/cwa-methods/whole-effluent-toxicity-methods.*

[11] Id.

[12] Three examples of longstanding policies include: EPA NPDES guidance documents (including WET documents): 1991 EPA Technical Support Document (TSD) for Water Quality-based Toxics Control (March 1991, EPA/505/2–90–001), EPA's Generalized Methodology for Conducting Industrial Toxicity Reduction Evaluations (TREs) guidance document (April 1989, EPA/600–2–88/070), and EPA's Toxicity Reduction Evaluation Guidance for Municipal Wastewater Treatment Plants (August 1999, EPA/833–B–99–002, revised edition from previous 1989 edition). See additional documents at *http://www.epa.gov/npdes/npdes-wet-programmatic-documents.*

EPA seeks comment on this proposed clarification of its current definition of WET.

3. Vessels Exclusion (40 CFR 122.3(a))

EPA proposes to revise § 122.3(a) to clarify which vessel discharges are excluded from the requirement to obtain NPDES permits.

The exclusion for discharges incidental to the normal operation of a vessel at 40 CFR 122.3(a), as it currently appears in EPA's regulations, was challenged in *Northwest Environmental Advocates et al.* v. *United States EPA,* 2005 U.S. Dist. LEXIS 5373 (N.D. Cal. 2005). On March 30, 2005, the court determined that the exclusion exceeded the EPA's CWA authority. In September 2006, the court issued a final order vacating the exclusion. *Northwest Environmental Advocates et al.* v. *United States EPA,* 2006 U.S. Dist. LEXIS 69476 (N.D. Cal. 2006).

EPA appealed the District Court's decision to the U.S. Court of Appeals for the Ninth Circuit, and on July 23, 2008, the Ninth Circuit upheld the decision. *Northwest Environmental Advocates* v. *EPA,* 537 F.3d 1006 (9th Cir. 2008). Effective December 19, 2008, except for those vessel discharges exempted from NPDES permitting by Congressional legislation, discharges incidental to the normal operation of vessels which had previously been excluded from NPDES permitting by 40 CFR 122.3(a) were subject to CWA section 301's prohibition against discharging, unless authorized by an NPDES permit. In response to the District and Court of Appeals decisions, EPA issued the Vessel General Permit (VGP) on December 19, 2008, which generally authorizes discharges incidental to the normal operation of commercial vessels that were no longer excluded from NPDES permitting as a result of the vacatur. In February 2013, EPA issued a new VGP, which replaced the 2008 VGP upon its expiration in December 2013. The 2013 VGP is currently in effect to authorize these discharges incidental to the normal operation of commercial vessels.

In late July 2008, Congress enacted two pieces of legislation to exempt discharges incidental to the normal operation of certain types of vessels from the need to obtain an NPDES permit. The Clean Boating Act of 2008 amended the CWA to provide that discharges incidental to the normal operation of recreational vessels are not subject to NPDES permitting, and are instead subject to a new regulatory regime to be implemented by EPA and the U.S. Coast Guard under a new section 312(o) of the CWA. S. 2766, Public Law 110–188 (July 29, 2008). As defined in section 3 of that law, which amends CWA section 502, "recreational vessel" means a vessel manufactured or used primarily for pleasure, or leased, rented or chartered to a person for the pleasure of that person. It does not include a vessel that is subject to Coast Guard inspection and is either engaged in commercial use or carries paying passengers. As a result of this legislation, discharges incidental to the normal operation of recreational vessels are not subject to NPDES permitting. EPA proposes adding a new subsection, 40 CFR 122.3(a)(2), to incorporate this statutory exemption.

The second piece of legislation provides for a temporary moratorium on NPDES permitting for discharges incidental to the normal operation of a vessel from (1) commercial fishing vessels (as defined in 46 U.S.C. 2101 and regardless of size) and (2) those other non-recreational vessels less than 79 feet in length. S. 3298, Public Law 110–299 (July 31, 2008). The statute's NPDES permitting moratorium ran for a two-year period beginning on its July 31, 2008 enactment date, during which time EPA studied the relevant discharges and prepared a report which was submitted to Congress in August 2010. Congress subsequently extended this moratorium to December 18, 2013 by Public Law 111–215. On December 18, 2014, President Obama signed into law the Howard Coble Coast Guard and Maritime Transportation Act of 2014, S. 2444, which extended the moratorium for an additional three years until December 18, 2017. EPA proposes text in 40 CFR 122.3(a) to reflect this law. The new proposed text also reiterates that the statute's NPDES permitting moratorium does not extend to ballast water discharges, or to other discharges that the permitting authority determines contribute to a water quality standards violation or which pose an unacceptable risk to human health and the environment.

EPA is also proposing an update to the existing exclusion to incorporate language regarding discharges incidental to the normal operation of vessels of the Armed Forces that was added to the CWA definition of "pollutant" after the promulgation of the original § 122.3(a) vessel discharge exclusion. Section 301(a) of the CWA provides that "the discharge of any pollutant by any person shall be unlawful" unless the discharge is in compliance with certain other sections of the Act, including the section 402 NPDES program. 33 U.S.C. 1311(a), 1342. Under CWA section 402(a), EPA may "issue a permit for the discharge of any pollutant, or combination of pollutants, notwithstanding section 1311(a)" subject to certain conditions required by the Act. The Act's definition of "pollutant" specifically excludes "sewage from vessels *or a discharge incidental to the normal operation of a vessel of the Armed Forces*" (emphasis added) within the meaning of CWA section 312. 33 U.S.C. 1362(6). The proposed change to § 122.3(a) reflects the statutory exclusion for discharges incidental to the operation of a vessels of the Armed Forces.

These changes would reduce confusion by accurately reflecting the current scope of the exclusion from NPDES permitting for discharges incidental to the normal operation of a vessel operating in a capacity as a means of transportation, which has narrowed since the exclusion was originally promulgated. These clarifications align with the decision in *Northwest Environmental Advocates* v. *EPA,* 537 F.3d 1006 (9th Cir. 2008), which vacated the § 122.3(a) exclusion from NPDES permitting for discharges incidental to the normal operation of a vessel. In addition, these clarifications incorporate or otherwise address CWA provisions that were enacted by Congress after the current regulations were promulgated.

EPA requests comments on whether the proposed changes to 40 CFR 122.3(a) accurately and clearly reflect the current law regarding which vessel discharges are subject to the NPDES permitting requirements. EPA does not seek and will not consider comments on aspects of 40 CFR 122.3(a) text that EPA does not propose to change, such as the discussion in the regulation of the types of vessel discharges that are not (and never have been) excluded from NPDES permitting under this regulation (*e.g.*, seafood processing vessels).

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[13] All state water quality standards include criteria for aquatic life protection. In all but one state, the water quality standards contain provisions to protect against both acute and chronic toxicity including sublethal endpoints in their narrative and/or numeric aquatic life protection criteria. One state, Iowa, has been working to revise its standards to include chronic toxicity including chronic sublethal endpoints but to date has acute endpoints (lethality) only.

4. Changes to Existing Application Requirements (40 CFR 122.21)

EPA proposes to update and clarify the permit application requirements in 40 CFR 122.21. As the NPDES program has evolved, many existing application requirements and associated forms have become outdated with respect to current program practices. Therefore, revisions to the application requirements at 40 CFR 122.21 and to the accompanying application forms are needed to update and improve their consistency, accuracy, and usability.

CWA section 304(i)(1) (previously section 304(h)(1)) required EPA to promulgate guidelines for "establishing uniform application forms and other minimum requirements for the acquisition of information" from point sources within 60 days after its enactment. In 1973, EPA promulgated short forms to meet these deadlines and standard forms to gather additional information from certain dischargers.

Amendments to the CWA in 1977 refocused EPA priorities on regulating toxic pollutants. As a result, the NPDES program expanded beyond regulating conventional pollutants to regulating toxic pollutants including certain metals and organic chemicals, and nonconventional pollutants such as ammonia, chlorine, and nitrogen.

To simplify permitting across several environmental programs, EPA published regulations on May 19, 1980 (45 FR 33290) to consolidate the requirements and procedures for five of the permit programs that EPA administers: The NPDES program, the Underground Injection Control (UIC) program under the Safe Drinking Water Act (SDWA), state "dredge or fill" programs under section 404 of the CWA, the Hazardous Waste Management program under the Resource Conservation and Recovery Act (RCRA), and the Prevention of Significant Deterioration (PSD) program under the Clean Air Act (CAA). This effort sought to eliminate gaps and overlaps and ensure consistency among the programs where appropriate.

At the same time, EPA consolidated the requirements and procedures for the five permit programs, it revised the permit application regulations. EPA created three new application forms: Form 1, Form 2B, and Form 2C. Form 1 requires general information about permit applicants and is required to be completed by applicants for each of the five types of permits under the consolidated permit rule. Form 2B is specific to NPDES permit applications for CAFOs and aquatic animal production dischargers. Form 2C applies to NPDES permit applications for manufacturing, commercial, mining, and silvicultural operations. All three forms reflected EPA's emphasis on toxic pollutants and other modifications to the CWA and NPDES program regulations.

Following promulgation of the consolidated permit regulations, interested parties commented that the consolidated format made the regulations unnecessarily difficult to use. They commented that dividing responsibilities among various entities at the state and federal levels caused additional problems. In practice, consolidated processing of multiple permits was rare because the various permit programs regulated different activities with different standards and thus imposed different types of requirements on permittees.

In response to problems permit writers encountered, EPA deconsolidated the five permitting programs on April 1, 1983 (48 FR 14146). The NPDES regulations remain in part 122 (substantive permit requirements) and part 123 (state program requirements). Part 124 (common permitting procedures) remains applicable to all of the programs. On September 1, 1983, EPA promulgated additional revisions covering a number of issues affecting the consolidated permit program. 48 FR 39611.

The NPDES program continued to use these application forms[14] (Form 1, Form 2B and Form 2C) after deconsolidation. In 1984, EPA amended Form 2C to include toxic pollutant sampling. In 1986, EPA promulgated two new NPDES forms: Form 2D for use by new manufacturing, commercial, mining, and silvicultural operations; and Form 2E for use by facilities that do not discharge process wastewater. 51 FR 26982.

In 1987, Congress made extensive revisions to the CWA. Water Quality Act (WQA), Public Law 100–4. A new provision, CWA section 402(p), required EPA to establish NPDES requirements for stormwater discharges in two phases. To implement these requirements, EPA published the Stormwater Phase I Rule which established permit application requirements for certain categories of stormwater discharges associated with industrial activity (creating Form 2F) and discharges from large and medium municipal separate storm sewer systems (MS4s). 55 FR 47990. On December 8, 1999, EPA published the Stormwater Phase II Rule regulating stormwater discharges from small construction sites and from certain small MS4s. 64 FR 68722.

In 1999, EPA also amended the permit application requirements and application forms for POTWs and treatment works treating domestic sewage (TWTDSs). 64 FR 42434. The new Form 2A for POTWs addressed a number of changes to the NPDES program that had occurred since 1973 (*e.g.*, toxics control, pretreatment programs, water quality-based permitting), and it streamlined the existing application requirements. The new Form 2S for TWTDSs addressed application requirements associated with new regulatory requirements for the generation, treatment, use and disposal of sewage sludge (biosolids). 58 FR 9248.

In 2000, EPA issued amendments to streamline the NPDES program in response to a Presidential Directive to review regulatory programs to eliminate any obsolete, ineffective, or unduly burdensome regulations. 65 FR 30886. As part of this streamlining effort, EPA revised several permit application provisions to reduce duplicative requirements and clarify certain application requirements.

On February 12, 2003, EPA issued a final rule revising NPDES requirements for CAFOs. 68 FR 7176. This rule revised the information requirements for entities seeking coverage under an NPDES permit for CAFOs, and revised the NPDES individual permit application for CAFOs (Form 2B for CAFOs and aquatic animal production facilities). Further, in response to an order issued in *Waterkeeper Alliance et al.* v. *EPA*, 399 F.3d 486 (2d Cir. 2005), EPA made several revisions to the CAFO regulations, including changes to the application requirements and Form 2B. 73 FR 70418.

On October 22, 2015, EPA's NPDES Electronic Reporting Rule went into effect, amending 40 CFR part 127. 80 FR 64063. This rule requires electronic submittal of NPDES permitting and compliance monitoring reporting information. This rulemaking changed the method by which information is provided by permittees to permitting authorities, expediting the collection and processing of data to create a consistent and transparent NPDES data set.

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[14] Forms 1, 2A, 2C, 2D, 2E, 2F, 2S (OMB Control No. 2040–0086); Form 2B (OMB Control No. 2040–0250).

EPA is proposing specific, targeted changes to the current application requirements and is not proposing, or seeking comment on, other changes to the information or pollutant screening data required by the existing regulations and forms. Several revisions included in this proposal are necessary in order to ensure the information required by the application forms across the different categories of facilities submitting applications is consistent with EPA's current data standards[15] and the NPDES Electronic Reporting Rule. EPA data standards promote efficient environmental information sharing among EPA, states, tribes, local governments, the private sector, and other information trading partners. These data standards are developed in collaboration with the Environmental Information Exchange Network (EIEN) and other federal agencies. Many of the application forms have not been updated in recent history to incorporate the data standards developed by this group.

EPA proposes updating the industrial code classification requirement to include the facility's North American Industry Classification System (NAICS) code, which is part of the established data standard.[16] Also, EPA proposes updating the latitude and longitude requirement to include the method of data collection, which is a required element in the current standard[17] and can be used to determine the reference datum that is in turn used in determining the latitude and longitude coordinates. In addition, EPA proposes revising the specificity of the latitude and longitude coordinates to provide consistency among forms in the level of information collected. Currently, some forms ask for latitude and longitude to the nearest second, and other forms ask more generally for just latitude and longitude. To ensure precision and improve consistency, EPA proposes revising the application forms and corresponding regulations in 40 CFR 122.21 to ask for latitude and longitude to the nearest second for every facility and permitted feature, as well as the method of collection for this information.

EPA proposes the following revisions to 40 CFR 122.21:

a. NPDES Contact Information—EPA proposes to update contact information for those interested in obtaining application forms. 40 CFR 122.21(a)(2) will be updated to: U.S. EPA, Mail Code 4203M, 1200 Pennsylvania Ave. NW., Washington, DC 20460 or by visiting *http://www.epa.gov/npdes*.

b. North American Industry Classification System (NAICS) Codes—For all applicants except publicly owned treatment works (POTWs) and treatment works treating domestic sewage (TWTDSs), EPA proposes to revise the requirements at 40 CFR 122.21(f)(3) to include NAICS codes, in addition to Standard Industrial Classification (SIC) codes, that reflect the products or services provided by the facility. This proposed revision would update the classification code requirement to be consistent with EPA's current data standard (NAICS) until EPA completely phases out the use of SIC codes in other program areas, such as the effluent guidelines program.

c. Latitude and Longitude—To improve the consistency and precision of locational information required in permit applications, and to be consistent with EPA data standards, EPA proposes several revisions:

i. For existing manufacturing, commercial, mining, and silvicultural dischargers, EPA proposes revising 40 CFR 122.21(g)(1) and 122.21(h)(1) to require outfall latitude and longitude to the nearest second, including the method of data collection (*e.g.*, global positioning system (GPS) device, topographical map and scale) in accordance with EPA data standards.

ii. EPA proposes revising 40 CFR 122.21(j)(1)(i) and 122.21(j)(3)(i) for new and existing POTWs, and 40 CFR 122.21(k)(1) for new sources and new discharges, to require the latitude and longitude of the discharging facility to the nearest second, including the method of data collection.

iii. For all applicants except POTWs and TWTDSs, EPA proposes to revise 40 CFR 122.21(f)(2) to require the latitude and longitude of the discharging facility to the nearest second, including the method of data collection. In addition, EPA is proposing to update the corresponding form (Form 1) to include a check box to indicate whether the location represents the primary entry point to the facility or the centroid of the facility site location.

iv. For new and existing concentrated animal feeding operations (CAFOs) and concentrated aquatic animal production (CAAP) facilities, EPA proposes revising 40 CFR 122.21(i)(1)(iii) to require latitude and longitude to the nearest second and the method of data collection.

v. For certain TWTDSs, EPA proposes revising the following paragraphs to require the site latitude and longitude to the nearest second including the method of data collection: 40 CFR 122.21(q)(1)(i), 122.21(q)(8)(ii)(A), 122.21(q)(9)(iii)(B), 122.21(q)(10)(iii)(B), 122.21(q)(11)(iii)(B) and 122.21(q)(12)(i).

vi. For combined sewer systems, EPA proposes revising 40 CFR 122.21(j)(8)(ii)(A)(3) to require the method of collection for the latitude and longitude of the combined sewer overflow (CSO) outfall.

vii. For cooling water intake structures, EPA proposes revising 40 CFR 122.21(r)(3)(ii) to require the intake structure latitude and longitude to the nearest second including the method of data collection.

EPA seeks comments on the availability of longitude and latitude coordinates for the specific locations identified above as well as whether there are any other considerations it should consider relating to submitting these coordinates as part of the application requirements.

EPA proposes revisions to the length of time given to new dischargers to submit effluent information. This revision would ensure that new dischargers submit effluent characterization data in a manner that is timely and consistent for both POTW and non-POTW dischargers. 40 CFR 122.21(k) currently requires new non-POTW sources to submit data within two years of the commencement of discharge, while 40 CFR 122.21(j) does not establish a timeframe for new POTWs to submit information. EPA's proposed revision would establish a new timeframe of 18 months for both POTW and non-POTW dischargers to submit effluent information to the permitting authority. Specifying a time frame for a POTW to submit actual monitoring results and reducing the time frame (from two years to 18 months) required for a new industrial discharger to submit actual monitoring results would ensure that permitting authorities have more timely access to actual effluent data upon which to confirm or rebut the estimates provided by new dischargers on their initial permit applications. While the estimates provided in the initial applications are useful and appropriate for determining the need for effluent limits, the actual effluent data are vital to confirm that permit conditions developed based on the estimated pollutant concentrations in fact protective of water quality. It is EPA's view that 18 months would provide a reasonable time period for a new discharge to collect representative effluent data and submit the data to the permitting authority. This 18 month timeframe would provide a new discharger with up to a three month time period to ensure that the treatment system is operating efficiently, collect data over a full calendar year, and have three months remaining to submit the data to the permitting authority. These revisions would not alter the type or quantity of information required from a new discharger, and impose no new burden.

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[15] For more information about EPA's Data Standards Program see *http://www.epa.gov/datastandards*.

[16] *http://www.exchangenetwork.net/standards/Facility_Site_01_06_2006_Final.pdf*.

[17] *http://www.exchangenetwork.net/standards/Lat_Long_Standard_08_11_2006_Final.pdf*.

EPA proposes the following revisions to 40 CFR 122.21:

d. New Discharger Data Submission—EPA proposes making the time provided for effluent data submission for new POTWs consistent with the requirement for new industrial dischargers. EPA also proposes to reduce the time period that is provided for new non-POTW dischargers to submit effluent data. Specifically, the proposed revisions to application requirements for new sources and new discharges at 40 CFR 122.21(k)(5)(vi) would require applicants to submit items V and VI of Form 2C no later than 18 months after the commencement of discharge. The current requirement for submission is two years. The proposed revisions to application requirements for new POTWs at 40 CFR 122.21(j)(4)(i) and 122.21(j)(5)(i) would require submission of data no later than 18 months after the commencement of discharge.

EPA specifically seeks comments on whether 18 months is an adequate period of time for new dischargers to submit effluent data.

EPA proposes revisions to the effluent data submission requirements for non-POTWs to be consistent with those for POTWs. The instructions for Form 2C currently direct applicants to provide all representative data where the applicant has multiple results for a particular parameter. The Form 2C instructions also indicate that data from the past three years should be included. These requirements are not specifically identified in the current regulations and the instructions are not consistent with the requirements for POTWs. When applying for an NPDES permit, an existing POTW must provide effluent data from the previous 4.5 years. The 4.5-year requirement for Form 2A was established to ensure the permittee summarizes all the data collected during its existing five-year permit term with consideration that the application would be submitted six months prior to the end of the permit term (*i.e.*, 4.5 years). It is EPA's view that summarizing the data from the previous permit term is equally as important for non-POTW dischargers. Accordingly, EPA proposes to revise the application Form 2C instructions as well as to include a new paragraph 40 CFR 122.21(g)(7)(ix) in the regulations to require the submission of effluent data representing the previous 4.5 years. These revisions would not alter the type or quantity of information required from a discharger, and impose no new burden.

EPA proposes the following revisions to 40 CFR 122.21:

e. Data Age for Permit Renewal—EPA proposes adding 40 CFR 122.21(g)(7)(ix) to ensure that the effluent data submission requirements for non-POTWs are consistent with those for POTWs. EPA proposes to revise the application Form 2C instructions and include a new paragraph in the regulations at § 122.21(g)(7)(ix) to require the submission of effluent data representing the previous 4.5 years for non-POTW facilities.

f. Reporting Electronic Mail Address—EPA proposes revising the following paragraphs in 40 CFR 122.21 to request the applicant's electronic mailing address (email): § 122.21(c)(2)(ii)(B), § 122.21(f)(4), § 122.21(j)(1)(ii), § 122.21(j)(1)(viii)(2) and (3), § 122.21(j)(9), § 122.21(q)(1)(i), § 122.21(q)(2)(i), § 122.21(q)(8)(vi)(A), § 122.21(q)(9)(iii)(D) and (E), § 122.21(q)(9)(iv)(A), § 122.21(q)(10)(ii)(A), § 122.21(q)(10)(iii)(K)(1), § 122.21(q)(11)(ii)(A), § 122.21(q)(12)(i), and § 122.21(q)(13).

EPA proposes specific targeted changes to the NPDES application requirements for POTWs that would bring the NPDES regulations in concert with changes to the general pretreatment regulations at 40 CFR 403.3(v). Application requirements at 40 CFR 122.21(j) ensure that POTWs submit information for both significant industrial users (SIUs) and categorical industrial users (CIUs), including industrial waste trucked or hauled to the POTW, in order to properly identify types of industries and characterize the wastewater discharged to the POTW. This application information is used by the pretreatment control authority to determine whether a pretreatment program must be developed. Control authorities are POTWs with an approved POTW pretreatment program, an authorized state pretreatment program, or EPA where there is no authorized state pretreatment program.

Prior to the 2005 national pretreatment program regulations revisions, all CIUs were considered a subset of the broader term "significant industrial users." In 2005, the general pretreatment regulation at 40 CFR 403.3(v) was revised to allow a control authority to designate certain CIUs, after qualifying and demonstrating continued compliance with categorical standards, as a non-significant CIU (NSCIU). 40 CFR 403.3(v)(ii). Users categorized as NSCIUs must submit an annual certification to maintain their "non-significant" status, but are no longer subject to annual sampling, inspections or permitting requirements such as local limits, which are required for significant users. This resulted in a reporting and permitting burden reduction on these CIUs and the control authorities. However, all CIUs (both those classified as SIUs and NSCIUs) are still subject to industrial sector-specific national categorical standards established in 40 CFR chapter I, subchapter N.

The proposed language at 40 CFR 122.21(j)(6) will clarify that POTWs are required to submit, as part of their application, relevant information from all industrial users (SIUs and NSCIUs). The proposed revision would align the NPDES application requirements with the existing pretreatment regulations at 40 CFR 403.3(v), and would impose no new burden.

EPA proposes the following revisions to 40 CFR 122.21:

g. Reporting Numbers of Significant Industrial Users (SIUs) and Non-Significant Categorical Industrial Users (NSCIUs)—EPA proposes revising 40 CFR 122.21(j)(6)(i) and (ii) to clarify that the reporting requirements under these sections apply to both SIUs and NSCIUs, including trucked or hauled waste, that discharge to a POTW.

EPA is also proposing to revise 40 CFR 122.21(f) to require applicants to indicate whether their facility uses cooling water and to identify the source of that cooling water. This would clarify the need for and ensure the permitting authority receives all of the necessary information required under existing 40 CFR 122.21(r) for the facility. This proposal will not alter any of the existing requirements under 40 CFR 122.21(r), and imposes no new burden.

EPA proposes the following revisions to 40 CFR 122.21:

h. Cooling Water Intake Structure Indication—EPA proposes adding a new paragraph 40 CFR 122.21(f)(9) to require the applicant to indicate whether the facility uses cooling water and to specify the source of the cooling water and to remind applicants they must comply with any applicable requirements at 40 CFR 122.21(r).

Finally, EPA proposes to revise §§ 122.21(f) and 122.21(j) to require applicants to indicate whether they are requesting any of the variances permitted under 40 CFR 122.21(m) (for non-POTWs) and (n) (for POTWs). This would ensure the permitting authority is aware of the request at the time of permit application and could better determine whether the facility has submitted all of the required information. This proposal would not alter any of the existing requirements of 40 CFR 122.21(m) and (n), and imposes no new burden.

EPA proposes the following revisions to 40 CFR 122.21:

i. Request for Variance Indication—EPA proposes adding a new paragraph 40 CFR 122.21(f)(10) to require the applicant to indicate whether he or she is requesting any of the variances under § 122.21(m). EPA also proposes adding 40 CFR 122.21(j)(1)(ix) to require the applicant to indicate whether he or she is operating under the variance for POTWs provided in § 122.21(n).

In this rulemaking, EPA is seeking comment only on these specific proposed targeted changes to the current application requirements. EPA is not proposing or seeking comment on other changes to the information or pollutant screening data that the existing regulations and forms require and will not respond to any such comments as part of this rulemaking. However, in the future, EPA may examine all the application forms to determine whether they should be revised further, for example, to address any potentially obsolete elements or information requests inconsistent with regulatory requirements at 40 CFR 122.21. If you would like to address changes to current application requirements other than those raised by this rulemaking, please submit those comments to Docket ID No. EPA–HQ–OW–2016–0146 at *http://www.regulations.gov.*

5. Antidegradation Reference (40 CFR 122.44(d))

EPA proposes to revise 40 CFR 122.44(d) to include a reference to 40 CFR 131.12 in order to ensure consistency with the state antidegradation requirements established under that section. CWA section 301(b)(1)(C) requires that NPDES permit limits be as stringent as necessary to meet water quality standards. Consistent with this requirement, the NPDES regulations at 40 CFR 122.44(d)(1) provide that NPDES permits shall include "any requirements in addition to or more stringent than promulgated effluent limitations guidelines or standards . . . necessary to: (1) Achieve water quality standards established under CWA section 303, including state narrative criteria for water quality." Water quality standards consist principally of three elements: Designated uses, water quality criteria and antidegradation policies. 40 CFR 131.6, 131.10–12. Pursuant to EPA's regulations at 40 CFR 131.12, states must adopt antidegradation policies. An antidegradation policy "specifies the framework to be used in making decisions about proposed activities that will result in changes in water quality" and "can play a critical role in helping states protect the public resource of water whose quality is better than established criteria levels and ensure that decisions to allow reductions in water quality are made in a public manner and serve the public good." NPDES PWM, 6.1.1.3. EPA expects permitting authorities to develop NPDES permit terms and conditions consistent with and in consideration of applicable state antidegradation policies and/or requirements. However, this interpretation has not explicitly been included in the NPDES regulations. The federal antidegradation policy has a long legislative history. The Secretary of the Interior established the basic federal antidegradation policy on February 8, 1968. When the CWA was enacted in 1972, the WQS of all 50 states included antidegradation provisions. By providing in 1972 that existing state WQS would remain in force until revised, the CWA ensured that states would continue their antidegradation programs. EPA's first WQS regulation, promulgated on November 28, 1975, included a similar antidegradation policy at 40 CFR 130.17. 40 FR 55,340–41.

Section 101(a) of the CWA emphasizes the prevention of water pollution and expressly includes the objective "to restore and *maintain* the chemical, physical and biological integrity of the Nation's waters" (33 U.S.C. 1251(a)) (emphasis added). The antidegradation requirements that EPA incorporated by regulation in 1983 into 40 CFR 131.12 implement the maintenance aspect of this CWA section 101(a) goal and are an essential component of the overall WQS program.

The CWA section 101(a)(2) goals call for the protection and propagation of fish, shellfish and wildlife, and recreation in and on waters. Although designated uses and criteria are the primary tools states use to achieve this goal, antidegradation complements these by, in part, providing a framework for maintaining and protecting waters that are of higher quality than necessary to support the CWA section 101(a)(2) goals, or are Outstanding National Resource Waters (ONRWs). Antidegradation plays a critical role in allowing states and tribes to maintain and protect the valuable resource of high quality water by ensuring that decisions to allow a lowering of high quality water are made in a transparent and public manner and are based on a sound technical record.

In the 1987 WQA, Congress expressly affirmed CWA section 101's antidegradation principle and referenced antidegradation policies in section 303(d)(4)(B) of the Act (33 U.S.C. 1313(d)(4)(B)), simultaneously confirming that antidegradation policies are an integral part of the CWA and explaining the relationship of antidegradation policies to other CWA regulatory programs:

> Standard Attained—For waters identified under paragraph (1)(A) where the quality of such waters equals or exceeds levels necessary to protect the designated use for such waters or otherwise required by applicable WQS, any effluent limitation based on a total maximum daily load or other waste load allocation established under this section, or any WQS established under this section, or any permitting standard may be revised only if such revision is subject to and consistent with the antidegradation policy established under this section.

As the Supreme Court stated in *PUD No. 1 of Jefferson County* v. *Washington Department of Ecology,* 511 U.S. 700, 705 (1994):

> A 1987 amendment to the Clean Water Act makes clear that section 303 also contains an 'antidegradation policy' . . . Specifically, the Act permits the revision of certain effluent limitations . . . only if such revision is subject to and consistent with the antidegradation policy established under CWA section 303, 33 U.S.C.1313(d)(4)(B)).

The court also acknowledged the long-standing federal antidegradation policy and EPA's authority to promulgate antidegradation requirements. Id. 704–05, 718.

Based on this authority, EPA promulgated its current antidegradation regulation at 40 CFR 131.12 on August 21, 2015. 80 FR 51020. Section 131.12 requires states to develop and adopt a statewide antidegradation policy and develop methods for implementing that policy. It built upon and refined the pre-existing 1983 regulation which EPA had promulgated at 40 CFR 131.12 on November 8, 1983. 48 FR 51400. Consistent with the Supreme Court decision, *PUD No. 1 of Jefferson County* v. *Washington Department of Ecology,* and the requirements of 40 CFR 131.12, WQBELs must be derived consistent with applicable state antidegradation policies. This is EPA's longstanding interpretation of the CWA. NPDES PWM, 6.1.1.3 and 7.2.1.4.

This interpretation is not expressly included in the existing regulations at 40 CFR 122.44(d)(1); thus, EPA now proposes to revise 40 CFR 122.44(d)(1) to expressly include a reference to 40 CFR 131.12, in order to ensure consistency with the antidegradation provisions in that section. Similar to the existing provision at 40 CFR 122.44(d)(1) noting that "narrative criteria for water quality" are components of water quality standards, including the reference to 40 CFR 131.12 serves notice that antidegradation policies are also components of state water quality standards and must be considered in in permitting decisions where applicable. EPA proposes revising 40 CFR 122.44(d)(1) to include, explicitly, "the state antidegradation requirement" as one of the elements of state WQS that must be applied when deriving WQBELs.

As noted above, because antidegradation is an existing component of all state WQS, the existing regulations at 40 CFR 122.44(d) require state and EPA permitting authorities to ensure that effluent limits derive from and comply with antidegradation requirements. EPA does not propose to change any of its existing interpretations of WQS, antidegradation or any related existing EPA interpretations of state implementation responsibilities. This proposed revision is intended solely as a clarification, and imposes no new burden. The only burden related to this new reference would be where state permitting authorities are not currently implementing elements of their EPA-approved WQS. It is EPA's view that currently, permit writers consider antidegradation, although NPDES permit records might not necessarily currently reflect this analysis.

EPA seeks comments on this proposed revision to 40 CFR 122.44(d)(1).

6. Dilution Allowances (40 CFR 122.44(d))

EPA proposes to revise 40 CFR 122.44(d) to specify that any allowance for dilution provided under this paragraph must comply with applicable dilution and mixing zone requirements and low flows established in state WQS[18] and be supported by data or analyses quantifying or accounting for the presence of each assessed pollutant or pollutant parameter in the receiving water.

The CWA and its implementing regulations require that NPDES permits include limitations as stringent as necessary to meet applicable WQS. CWA 301(b)(1)(C); 40 CFR 122.44(d)(1). When determining the need for conditions necessary to meet WQS, 40 CFR 122.44(d)(1)(ii) indicates that the permitting authority shall consider, "where appropriate, the dilution of the effluent in the receiving water." When developing WQS pursuant to CWA section 303(c), EPA regulations at 40 CFR 131.13 provide that states may include in the state standards "general policies" affecting the application of WQS such as mixing zones, low flows and variances. Alternatively, states may address dilution and mixing considerations through implementation policies and guidance. Consistent with these provisions, many state WQS and implementation procedures allow some consideration of dilution and mixing when determining the need for and calculating WQBELs.

The ambient environment mitigates the impact of an effluent discharge on a receiving water in a number of ways, generally related to the nature of the discharged pollutant and the physical, chemical and biological characteristics of the effluent and receiving water. For many toxic pollutants, dilution is the primary mitigation mechanism. For oxygen-demanding pollutants, such as biochemical oxygen demand (BOD), mitigation may be achieved through both dilution and biodegradation. For other pollutants, mitigation may be achieved through multiple processes, including dilution, biodegradation, chemical reactivity and volatilization. The concentration or mass of a pollutant or pollutant parameter that can be safely mitigated by these various processes in the receiving water without exceeding any applicable WQS and without causing adverse effects is commonly referred to as the "assimilative capacity" of the receiving water.

For any consideration of the dilution of an effluent in a receiving water, modelers must account for the level of the pollutant already present in the receiving water prior to the introduction of the effluent. This is often referred to as the "background" pollutant concentration. The background pollutant concentration can be based on measurements from the receiving water, or where data are unavailable, can be assumed. Where data are available, modelers assess the data and select a value that is considered representative of the site. The selection of the background value might be based on an average of the data, or on an upper or lower statistical boundary, and is generally a matter of state policy or procedure. In any case, modeling requires that the modeler select some background pollutant value.

Where no measured data are available, the modeler could either postpone the analysis to obtain data, or could instead assume a background concentration. For NPDES permitting purposes, the assumed background value could range from zero to a value at or above the applicable water quality criteria. An assumption of zero indicates that the full assimilative capacity of the water is available, while an assumption that the background concentration is at or above the applicable water quality criteria indicates that there is no remaining assimilative capacity. As noted above, the selection of one of the end point values, or some value between these two extremes, is typically a matter of state policy.

As discussed above, granting any dilution allowance requires the consideration of the background pollutant concentration. NPDES permit reviews have shown that in many instances permitting authorities grant dilution allowances for pollutants assuming the complete absence of the pollutant in the upstream receiving waters. An assumption of "zero background" levels of a pollutant in an upstream water, in the absence of data or analyses to validate such an assumption, results in permit conditions that use as much as 100 percent of the receiving water's dilution capacity to the discharging facility. Thus, in situations where some of the pollutant is actually present in the upstream waters, an assumption of "zero background" concentration overestimates the available assimilative capacity of the receiving water and could result in limits that are not protective of applicable WQS. EPA has long intended that permit writers should consider information regarding the actual assimilative capacity of the receiving waters and the amount of the pollutant already present in the receiving water when determining dilution allowances and mixing zones.

The current regulations allow consideration of dilution ". . . where appropriate." However, the current provision does not indicate what is meant by "appropriate." EPA proposes to update its NPDES regulations concerning dilution allowances to clarify that while existing regulations allow consideration of dilution "where appropriate," any allowance for dilution and mixing must be applied in a manner that will ensure that NPDES permits contain limits necessary to achieve WQS, as required by CWA 301(b)(1)(C) and 40 CFR 122.44(d)(1). This proposal is consistent with EPA's longstanding guidance[19] that assumptions regarding dilution and mixing are appropriate only where relevant data or information are available to substantiate the assumption.

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[18] See 40 CFR 131.13 ("States may, at their discretion, include in their State Standards, policies generally affecting their application and implementation, such as mixing zones, low flows and variances.").

EPA proposes clarifying 40 CFR 122.44(d)(1) to specify that the appropriateness of any consideration of dilution or mixing must derive from the applicable state WQS, including any general policies related to dilution and mixing. Further, the proposed revision to 40 CFR 122.44(d)(1) would require that decisions regarding the assimilative capacity of the receiving water, for the purpose of determining a dilution allowance, must be supported by data or analyses quantifying or accounting for the presence or absence of each assessed pollutant or pollutant parameter in the receiving water. Conducting a basic background inquiry into a receiving water's assimilative capacity would be necessary to grant the dilution allowance. Where the actual assimilative capacity of the receiving water cannot be accurately determined or predicted (*e.g.*, by using data, models, or analyses), the permitting authority would be expected to establish effluent limits based on the application of applicable water quality criteria at the point of discharge (often referred to as "criteria end-of-pipe") in order to ensure that the limits comply with CWA section 301(b)(1)(C).

This revision would ensure that the permitting authority considers data or other available and applicable information before granting a dilution allowance for either rapid and complete or incomplete mixing. Under the proposed revisions, every time a dilution allowance is granted, assuming either rapid and complete or incomplete mixing, the permitting authority would be required to include a basis grounded in analyses of available information. This revision would not require the collection of new data and will not impose a new burden; it is intended to ensure that the permitting authority considers existing valid and representative ambient water quality data and to enhance decision-making transparency when permitting authorities consider a dilution allowance. States also may choose to collect data and information on the receiving water from the applicants, either prior to issuance of the permit or as a condition of the permit. Potential sources of data and information on ambient water quality and flow are maintained by regulatory agencies such as EPA, the United States Geological Survey (USGS) and state-level authorities. Dischargers, monitoring consortia, or non-governmental organizations may also provide ambient monitoring data for these analyses, although permitting authorities should ensure that all data used in any dilution analysis are subject to quality assurance and quality control. In limited circumstances (*e.g.*, where ambient data are unavailable), permitting authorities may satisfy this requirement by conducting a qualitative analysis of the ambient level of a pollutant of concern; however, the analysis must be pollutant- and site-specific, supported by the available information and documented in the record consistent with the revised provisions at 40 CFR 124.56(a)(1)(iv).

EPA seeks comments on this proposed revision to 40 CFR 122.44(d).

7. Reasonable Potential Determinations for New Discharges (40 CFR 122.44(d))

EPA proposes to revise 40 CFR 122.44(d) to specify that a "reasonable potential" determination (explained below) must consider relevant qualitative or quantitative data, analyses, or other valid and representative information for pollutants or pollutant parameters that could support the need for effluent limitations for new discharges.

Where TBELs are not sufficient to attain applicable WQS, CWA section 301(b)(1)(C) requires that permits include any more stringent limits necessary to meet such standards. 40 CFR 122.44(d)(1). These limits are known as water quality-based effluent limits, or WQBELs. EPA regulations state that "[l]imitations must control all pollutants or pollutant parameters (either conventional, nonconventional, or toxic pollutants) which the Director determines are or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any [s]tate water quality standard, including [s]tate narrative criteria for water quality." 40 CFR 122.44(d)(1)(i). Based on this language, EPA refers to the process that a permit writer uses to determine whether a WQBEL is required in an NPDES permit as a reasonable potential analysis. NPDES PWM, 6.3.1. However, the current regulatory language is unclear regarding the types and quantities of data and information (including qualitative information) permitting authorities must consider when conducting a reasonable potential analysis. Because of this lack of clarity in the regulations, EPA has found that permitting authorities often defer the reasonable potential determination and development of WQBELs until a minimum data set has been collected. Permit reviews have also revealed a lack of reasonable potential determinations where quantitative data was not yet available, despite the availability of studies and effluent analyses for facilities with similar operations and effluent characteristics.

Permit writers must determine whether the limits and conditions of an NPDES permit are as stringent as necessary to attain any applicable WQS. CWA section 301(b)(1)(C). Once the permitting authority determines that a discharge causes, has the reasonable potential to cause, or contributes to an excursion above water quality criteria, 40 CFR 122.44(d)(1) requires the permitting authority to develop effluent limits to control the discharge of such pollutant(s). The cumulative impact of point and nonpoint sources on a water body may cause an excursion. In determining the need for a permit limit, the permitting authority must, at a minimum, consider existing controls on both point and nonpoint sources of pollution, the variability of the pollutant or pollutant parameter in the effluent, the sensitivity of the involved species to toxicity testing (when evaluating WET), and where appropriate, the effluent dilution in the receiving water. 40 CFR 122.44(d)(1)(ii). EPA's TSD specifically discusses conducting a reasonable potential evaluation in the "absence of effluent data." These factors include the type of discharge, the available dilution, the type of receiving water and designated use, existing data on toxic pollutants and the history of compliance problems and toxic impact. TSD 3.2. The NPDES PWM similarly suggests that permit writers use "any available effluent and receiving water data as well as other information pertaining to the discharge and receiving water," including type of industry, existing TBELs, compliance history and stream surveys. NPDES PWM, 6.3.2.

Consistent with this existing guidance and policy, this proposal would require the Director to make a reasonable potential determination based on relevant qualitative or quantitative data, analyses or other valid and representative information for pollutants or pollutant parameters that could support the need for effluent limitations. When determining effluent limitations for new dischargers where effluent data is not yet available, permitting authorities can use existing monitoring data and other studies that have been conducted at similar facilities. The existing application form(s) for new dischargers specifically require applicants to describe their planned flows, sources of pollution, and treatment technologies for each proposed outfall and to provide estimates of the concentrations of pollutants expected to be present in the effluent upon commencement of discharge. Applicants must also provide the name and location of any existing plant(s) which resemble the proposed facility with respect to production processes, wastewater constituents, or wastewater treatments. In addition, if an applicant is in an industrial category for which EPA has developed effluent limitations guidelines (ELGs), EPA has published development documents for every approved guideline[20] that provides detailed effluent characterization data that can be used to estimate the types and quantities of pollutants that might be discharged.

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[19] TSD Section 4 and Responsiveness Summary. See also EPA NPDES Permit Writers Manual (2010) Section 6.2 and EPA Water Quality Standards Handbook, Chapter 5 (General Policies).

This proposed revision would codify EPA's long-standing policy that the permitting authority should consider available and relevant data and information (as described above) pertaining to the discharge in order to make an informed judgment.[21] This proposed change would ensure that permitting authorities consider a wide range of available information to characterize new and existing discharges to determine the need for permit limits that adequately protect WQS. This revision would not require collecting new data beyond that already required through permit applications and would ensure that the permitting authority is transparent in its decision-making process when determining the need for an effluent limit, even for applicants that have yet to commence discharge. This proposal would not require collecting new data. However, this proposed revision would codify EPA's long-standing policy and guidance that, while the permitting authority has the discretion to prioritize the importance of available and relevant data and information used in making a determination on a case-by-case basis, it may not disregard valid information that is useful in conducting a reasonable potential analysis.

EPA seeks comments on this proposed revision to 40 CFR 122.44(d).

8. Best Management Practices (BMPs) (40 CFR 122.44(k)(4)

(a) Contact Information

EPA is correcting publication contact information included in the Note to § 122.44(k)(4) by deleting outdated references to information sources that are no longer available to read: "Additional technical information on BMPs and the elements of BMPs is contained in the following documents: Guidance Manual for Developing Best Management Practices (BMPs), October 1993, EPA No. 833/B–93–004, NTIS No. PB 94–178324, ERIC No. W498); Storm Water Management for Construction Activities: Developing Pollution Prevention Plans and Best Management Practices, September 1992, EPA No. 832/R–92–005, NTIS No. PB 92–235951, ERIC No. N482); Storm Water Management for Construction Activities, Developing Pollution Prevention Plans and Best Management Practices: Summary Guidance, EPA No. 833/R–92–001, NTIS No. PB 93–223550; ERIC No. W139; Storm Water Management for Industrial Activities, Developing Pollution Prevention Plans and Best Management Practices, September 1992; EPA 832/R–92–006, NTIS No. PB 92–235969, ERIC No. N477; Storm Water Management for Industrial Activities, Developing Pollution Prevention Plans and Best Management Practices: Summary Guidance, EPA 833/R–92–002, NTIS No. PB 94–133782; ERIC No. W492. EPA guidance documents can be obtained through the National Service Center for Environmental Publications (NSCEP) at *http://www.epa.gov/nscep.* In addition, States may have BMP guidance documents."

9. Anti-Backsliding (40 CFR 122.44(l))

EPA proposes to revise 40 CFR 122.44(l) to incorporate the anti-backsliding provisions that are currently in the CWA and have not yet been incorporated into the NPDES regulations. As a general matter, the anti-backsliding provisions prohibit the renewal, modification or reissuance of an NPDES permit with effluent limitations that are less stringent than the effluent limitations that existed in the prior permit. Anti-backsliding requirements are found in the CWA in sections 402(o) and 303(d)(4) and in the NPDES regulations at 40 CFR 122.44(l).

EPA revised the existing regulatory language at 40 CFR 122.44(l) in January 1989 under the 1987 WQA. 54 FR 245. The WQA amended the CWA to include sections 402(o) and 303(d)(4). EPA's 1989 regulatory revision did not, however, incorporate the entirety of the WQA's provisions on anti-backsliding. The proposed revision would incorporate into the NPDES regulations the omitted WQA anti-backsliding provisions applicable to effluent limitation.

The following is a list of the anti-backsliding sections and where EPA proposes to incorporate them into the regulation: The second sentence of CWA section 402(o)(1) would be incorporated into 40 CFR 122.44(l) as a new section 122.44(l)(2); the second sentence of CWA section 402(o)(2)(E) would be incorporated into 40 CFR 122.44(l) as a note at the end of § 122.44(l)(2); and CWA sections 303(d)(4)(A) and 303(d)(4)(B) would be incorporated into 40 CFR 122.44(l) as new §§ 122.44(l)(3)(i) and 122.44(l)(3)(ii), respectively. In each case, EPA is incorporating statutory language verbatim.

Since EPA is including anti-backsliding statutory language verbatim, EPA is not seeking comments on the added language or on the existing regulation.

10. Design Flow for POTWs (40 CFR 122.45(b))

EPA proposes revisions to 40 CFR 122.45(b) to clarify that permit writers would be required to calculate permit effluent limits for POTWs using design flow only where the limits are based on technology standards. The revisions would provide permit writers with additional flow options for calculating WQBELs. The existing regulation applies to production-based limits and currently states that POTW permit effluent limitations, standards or prohibitions shall be calculated based on design flow. The current regulation at 40 CFR 122.45(b)(2)(i) provides that for dischargers other than POTWs, permit effluent limitations, standards or prohibitions shall be based upon "a reasonable measure of actual production of the facility." This has led to some confusion as to whether the requirement for POTW "production-based" limits should be applied to the calculation of WQBELs. This requirement pre-dates EPA's current WQBEL regulations developed to address the 1987 WQA. The administrative record for the existing regulations provides no indication that the production-based requirement was intended to apply to the calculation of WQBELs.

The CWA does not provide any indication that WQBELs for POTWs should be derived in a manner that is distinct from other categories of dischargers. When determining the need for WQBELs or calculating WQBELs for any type of discharger, permitting authorities generally use data and analyses to predict the impact of a discharge on a receiving water. In conducting these analyses, permitting authorities use data (including effluent flow values) that most accurately reflect the conditions in the discharge and the receiving water. Because there is no inherent difference in the validity and process for modeling POTW versus non-POTW discharges, EPA has concluded that the option to use effluent flows other than design flow should be made available to permit writers when calculating WQBELs for POTWs.

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[20] *http://www.epa.gov/eg/industrial-effluent-guidelines.*

[21] TSD section 3.2. See also *Final Guidance on Appalachian Surface Coal Mining,* 2011: "[i]n conducting a reasonable potential analysis, all valid representative qualitative and quantitative information regarding the effluent and receiving water should be used.".

Where the POTW limits are water quality-based, such limits could be based on effluent flows other than design flow (*e.g.,* actual flow, estimated flow). Therefore, EPA proposes to clarify that permitting authorities developing WQBELs for POTWs have the same flexibility to base calculations on effluent flows as they do for the development of WQBELs for all other dischargers.

This option would be appropriate when modeling the impact of any type of pollutant, including when BOD and suspended solids are used as surrogate parameters for applicable WQS. Although this proposal would clarify this flexibility for POTWs, it is not intended to preclude or restrict a permitting authority from using the POTW design flow for the purpose of developing WQBELs. In many cases, the POTW design flow is a reasonable and appropriate value for use in water quality modeling, and this proposed clarification is not intended to discourage permitting authorities from current practices under which design flow is used for WQBEL development. This proposed revision provides additional flexibility for permit writers in calculating effluent limitations and will not impose new burden.

EPA seeks comments on this proposed revision.

B. Proposed Revisions to Part 123

1. Objection to Administratively Continued Permits (40 CFR 123.44)

EPA proposes revising 40 CFR 123.44 to allow EPA to designate certain administratively continued permits as "proposed permits."

Section 402(d) of the CWA generally provides that authorized state NPDES permitting authorities should submit proposed state permits to the EPA Administrator for review and objection, where deemed appropriate. 40 CFR 123.44. MOAs between EPA and the authorized state provide the timeframe within which each EPA Regional Administrator (RA), to whom the review and objection duties have been delegated, may comment on or object to a proposed permit, up to 90 days from receipt of the proposed permit. Within this time period, the RA must submit to the State Director a statement of the reasons for any objection, and the effluent limitations and conditions that such permit would include if it were issued by the RA.

When a permittee has submitted a timely and complete renewal application but the State Director has not acted on the permittee's application before the existing permit expires, state laws often provide that the existing permit continues in effect by operation of law until the state takes final action on the permittee's application (that is, until the state makes a final decision to issue or not issue the new permit). This is often referred to as "administrative continuance." These state laws, like the corresponding federal provisions in 40 CFR 122.6 and the federal Administrative Procedure Act (APA) at 5 U.S.C. 558(c), aim to protect a permittee that has submitted a timely and complete application for renewal from losing its authorization to discharge simply because the permitting authority did not issue a new permit before the existing permit expired.[22]

In some cases, administratively continuing expired permits provides states with flexibility to prioritize their action without significant adverse impacts on receiving waters. However, administrative continuance also can lead to inappropriate delays in reissuing permits that need revision to comply with current regulatory and statutory requirements and policy practices. State administrative continuance laws typically allow an expired permit to remain administratively continued indefinitely, which can significantly delay the implementation of revised or new effluent limitations (both technology-based and water-quality based). Under EPA's existing regulations, there is no mechanism by which to invoke EPA's permit review and objection authority to avoid indefinite delays in permit reissuance. A lengthy administrative continuance of a permit can significantly delay implementation of new effluent guidelines, WQS or TMDLs, and such a delay can affect a permitting authority's ability to protect water quality. As of September 2015, there were approximately 17,000 facilities covered by expired non-tribal and tribal permits (both state and EPA-issued, not including facilities covered by non-major stormwater permits).

Under this proposed revision, expired permits that have been administratively continued and are considered environmentally significant may be subject to objections by EPA regional offices. EPA would expect to exercise this authority only in very limited circumstances, such as for permits involving environmental and public health issues, where other means of working with the state to reissue an updated permit have failed. Under the current regulations, the RA may review and object to an NPDES permit that an authorized state proposes to issue. 40 CFR 123.44. EPA proposes adding a new mechanism that grants the RA discretion to initiate these procedures where the state has not reissued an expired, administratively continued permit. The RA would have discretion to exercise this authority if a state does not produce a draft permit within a certain period of time, as described below. If a state has not reissued an expired, administratively continued permit, the state would be encouraged to explain to EPA the reasons for not reissuing the expired permit and EPA would carefully consider any such explanation before proceeding with an objection, as further described below.

Consistent with 40 CFR 122.6(d), which currently addresses administratively continued permits, the proposed regulation would apply to only those expired state-issued permits for which state law has provided for continuation of the expired permit. The new provision would not apply to expired permits that have not been administratively continued, nor would it apply to other unpermitted discharges. A similar regulatory change allowing for EPA objection to administratively continued permits, under certain conditions, was previously proposed, commented on and finalized as a part of EPA's July 2000 Total Maximum Daily Load (TMDL) Rule. 68 FR 13608. However, the final rule was withdrawn in March 2003 as a result of widespread controversy and disagreement over the rule and its legal authority, including a case filed in the D.C. Circuit Court.[23] It is important to note, however, that the TMDL rule and disagreement over its legal authority were not based on concerns regarding the proposed section on administratively continued permits.

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[22] 40 CFR 122.21(d)(2) requires that an existing permittee submit a new permit application 180 days before an existing permit expires.

[23] See, *American Farm Bureau Federation* v. *Whitman* (D.C. Cir. No. 00–1320 and consolidated cases).

In fact, many of the comments received by EPA expressed support for this proposed revision. EPA received a number of comments stating that EPA has an obligation under the CWA to ensure that all state programs and state-issued permits comply with the requirements of the Act. Some expressed the view that the language proposed in the 2000 rule was unduly limited, because it would have limited EPA's review of expired permits to only those expired permits authorizing discharges to waters that do not attain and maintain WQS, and that EPA should be allowed instead to review and potentially object to, if necessary, all administratively continued permits, not just those permits for which WQS and TMDLs are of concern.

Given the current backlog of administratively continued state permits, EPA views this proposed revision as providing an important potential mechanism through which to carry out its authorities under the CWA. 33 U.S.C. 1361(a). Under CWA section 402(c)(2), authorized state programs must comply with the requirements of the Act including CWA section 402(b)(1)(B), which provides that NPDES permits may not be issued for periods exceeding five years. The purpose of this statutory limitation is to ensure that permits be reviewed and revised regularly by the state, and by EPA in its CWA 402(d) oversight role, to ensure compliance with the Act and its implementing regulations, including those pertaining to both TBELs and WQBELs.[24] The proposed revision would provide EPA with the ability to further this Congressional intent to protect water quality by ensuring that permitting authorities consider effluent guidelines, WQS, and TMDLs that have been promulgated since the existing administratively continued permit was issued.

EPA currently addresses expired, administratively continued permits through its "priority permits" measure. Priority permits are those permits that have been expired longer than two years, and which EPA has asked the permitting authority to target for reissuance. EPA's general trigger for identifying priority permits is when a permit is expired two years (outlined in a 2004 memorandum from the Director of EPA's Office of Wastewater Management to EPA's Regional Water Division Directors on the topic of permit issuance, priority permits and permitting backlog).[25]

EPA proposes that an administratively continued permit could be designated as "proposed" after either a two-year or five-year period following the initial five-year permit term, and is seeking comment on which time frame is appropriate. A two-year period after which an administratively continued permit could be designated by EPA as "proposed" would be consistent with EPA's general trigger for identifying priority permits. EPA's view is that it is reasonable to consider a two-year delay as an indication that the state is unable to take action on the permit. A five-year period after which an administratively continued permit could be designated as "proposed" would allow for EPA to first address the administratively continued permit through the priority permits measure. A five-year expired permit would be designated as a priority permit after being expired for two years, and the state would have had at least three additional years to work on and reissue the permit. Additionally, a five-year expired permit would have been expired for an entire permit cycle. EPA's view is that it is reasonable for a state to take action to reissue a permit that has been expired and administratively continued for five years.

EPA expects to exercise its discretion to use this authority only in very limited circumstances, such as for particularly environmentally significant permits, to ensure that these expired permits may be reissued in a timelier manner and, when reissued, reflect the most current statutory and regulatory requirements. EPA has used the priority permits measure since 2004 to target administratively continued permits which should be a priority for reissuance. The parameters by which permits generally may be designated as priority permits were identified in the above referenced 2004 memorandum, which is included in this rule's docket. EPA is considering using similar parameters to identify permits for candidates for administratively continued permit objections. Under this approach, permits with the following significant adverse impacts, changes or issues could be potential candidates for the new objection process:

- New or revised water quality standards;
- New or revised effluent limitations guidelines;
- Potentially significant impacts to an impaired or threatened waterbody;
- Potentially significant impacts to a drinking water resource;
- National program priorities (*e.g.,* Combined Sewer Overflow, Concentrated Animal Feeding Operations);
- Protection of threatened or endangered species;
- Significant changes to a facility's operations, treatment, or effluent characteristics; or
- Public concerns or environmental justice issues.[26]

Under the proposed provision, EPA would be required to give the state and the permittee notice of its intent to designate the administratively continued permit as a proposed permit submitted to EPA for review under 40 CFR 123.44. EPA proposes to give the state and the permittee 180 days' notice of its intent to designate an administratively continued permit as a proposed permit, and is requesting comment on whether this time frame is appropriate. This proposed provision would not create a new mechanism for EPA to take over a state's NPDES permit. During EPA's review of the "designated" proposed permit, the state permitting authority may decide to proceed with the development of its own draft or proposed permit. EPA would encourage this effort, as the intent is always to have a state permitting authority reissue an administratively continued permit incorporating all of the appropriate terms and conditions. For this reason, the proposed amendment provides that if the state, under 40 CFR 123.43(a), submits a draft or proposed permit for EPA review at any time before authority to issue the permit would pass to EPA under 40 CFR 123.44(h), EPA would withdraw its designation of the administratively continued permit as a proposed permit. EPA would then review the state's draft or proposed permit in accordance with the 40 CFR 123.44 procedures. If, after EPA reviews the permit under 40 CFR 123.44, the state does not proceed with the timely issuance of the final permit (within 180 days of the completion of EPA's review), EPA may again determine that the state does not intend to reissue the permit and may reassert its previous determination that the administratively continued permit is to be designated as a proposed permit. EPA would then proceed with the review of the designated "proposed" permit at the point in the process where the state submitted its draft or proposed permit.

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[24] See 33 U.S.C. 1311(b)(1)(C) (requiring that "there shall be achieved . . . any more stringent limitation, including those necessary to meet water quality standards, treatment standards, or schedule of compliance, established pursuant to any State law or regulations . . . or any other federal law or regulation, or required to implement any applicable water quality standard established pursuant to this Act").

[25] Jim Hanlon, "Permitting for Environmental Results: Permit Issuance and Priority Permits," March 5, 2004, available at *http://www3.epa.gov/npdes/pubs/prioritization_memo3-5-04.pdf.*

[26] Id.

EPA is seeking comments on whether to make this proposed regulatory change. Specifically, EPA seeks comments on whether considering administratively continued permits as "proposed permits" under CWA section 402(d) would effectively achieve EPA's goal of more timely reissuance of state NPDES permits, or whether EPA should consider other regulatory mechanisms to achieve this goal. EPA is also seeking comment on the potential parameters or criteria that EPA could use to more clearly define or limit the scope of this administratively continued permit objection process, including but not limited to those described in the memorandum referenced above, and whether any such parameters or criteria should be included in regulatory language. Additionally, EPA seeks comments on whether two years, or five years, or some other time period is the appropriate threshold at which EPA may designate an administratively continued permit as a proposed permit for the purposes of exercising its objection authority, and whether the proposed 180 days or some other period of time is an appropriate notice period for EPA to notify the state and permittee of its intent to designate the administratively continued permit as a proposed permit. Specifically, if commenters believe other time periods for designating proposed permits and providing notice would be appropriate, EPA requests comments describing the reasoning for such time frames.

C. Proposed Revisions to Part 124

1. Public Notice Requirements (40 CFR 124.10(c))

EPA proposes revising 40 CFR 124.10(c) to allow permitting authorities to provide public notice of permitting actions for NPDES major individual and general permits on the permitting authority's publicly available Web site in lieu of the newspaper publication requirement.

CWA section 402(b)(3) requires that notice be provided to the public, as well as any other state whose waters may be affected, of each NPDES permit application and that an opportunity be provided for a public hearing before ruling on each permit application. 33 U.S.C. 1342(a)(1). In addition, the statute provides that "public participation in the development, revision and enforcement of standard, effluent limitation, plan, or program established by the Administrator or any State under [the CWA] shall be provided for, encouraged, and assisted by the Administrator and the States." 33 U.S.C. 1251(e). EPA's regulations also address the issue of public participation in its programs. 40 CFR 124.10. 40 CFR part 25 sets forth minimum requirements for public participation under the CWA, RCRA and SDWA. 40 CFR 25.4(b) explains that "providing information to the public is a necessary prerequisite to meaningful, active public involvement. Agencies shall design informational activities to encourage and facilitate the public's participation in all significant decisions . . . particularly where alternative courses of action are proposed." These minimum requirements are intended to be met not only by EPA but also by authorized states and state agencies. In clarifying the minimum requirements for public participation, 40 CFR part 25 highlights that the requirements for public information, public notification and public consultation are "intended to foster public awareness and open processes of government decision making and are applicable to all covered activities and programs." 40 CFR 25.3(c)(7) specifically emphasizes that agencies should "use all feasible means to create opportunities for public participation, and to stimulate and support participation." Neither the CWA nor its implementing regulations specify the best or preferred method for providing notice to the public.

Currently, 40 CFR 124.10(c)(2)(i) requires notice of specified NPDES permitting activities, such as preparation of a draft permit, through publication "in a daily or weekly newspaper within the area affected by the facility or activity." Indeed, publication of public notice in newspapers was appropriate when 40 CFR 124.10(c)(2)(i) was promulgated in 1982, 12 years before the internet became widely available for public and commercial use. Web sites are often more appropriate avenues for widely disseminating information to the public and many states currently supplement the required newspaper publication by posting draft and final permits on their state Web sites.

EPA proposes revising 40 CFR 124.10(c) to allow permitting authorities (EPA, state, tribe and territories) to provide public notice for activities listed under 124.10(a) on the permitting authority's publicly available Web site in lieu of the newspaper publication requirement. If a permitting authority exercises this option, the permitting authority would be required to meet all of the required elements of § 124.10(c) and also post all draft permits and fact sheets on the Web site during the public comment period and post all final permits, fact sheets and response to comments on the Web site for the entire term of the permit. The purpose of this revision would be to provide states and EPA with an alternative method of providing notice of permit applications and hearings, and affirm flexibility in reaching the public through a variety of methods that would greatly expand public access to the draft and final permits and fact sheets.

This option would not in any way affect the requirements of 40 CFR 124.10(c)(1)(ix) which state that a copy of the notice must be mailed directly to persons who have joined the appropriate mailing list. This option also would not alter the original requirements of 40 CFR 124.10(c)(2)(i) if a permitting authority chooses to continue the traditional method of providing notice of an NPDES permit action in a newspaper publication. Also, this option would not alter the existing requirements for other types of permits covered in this section (*i.e.* RCRA, UIC, section 404). In addition, none of the other existing public notice regulatory requirements would be affected by this proposed revision to 40 CFR 124.10(c). The proposed revision is intended to supplement and expand EPA's efforts to reach communities through a variety of methods. By allowing each permitting authority to determine whether newspaper publication, internet notice, or a combination of these methods is the most effective method for its communities, EPA expects an increase in effective dissemination of information to communities and transparency.

Finally, nothing in the proposed revisions to 40 CFR 124.10(c) is intended to alter or affect the notice requirements for issuance of a final permit decision in 40 CFR 124.15. Section 124.10(a) establishes notice requirements as to certain enumerated actions, but those actions do not include "issuance" of a final permit decision, the requirements for which are established in 40 CFR 124.15. The inclusion in the proposed revision to 40 CFR 124.10(c) of an internet posting requirement in certain circumstances for final permits is not intended to imply that internet posting fulfills the final permit decision notice requirements of 40 CFR 124.15.

EPA is seeking comment on an alternative option for revising 40 CFR 124.10(c) that would *require* NPDES permitting authorities to public notice *all* NPDES permits and hearings on the permitting authority's publicly available Web site. This option could be implemented over a period of time (*e.g.,* within five years), and states would continue to have the flexibility to use print media and other methods in addition to the publicly available Web site. It could include a provision allowing NPDES permitting authorities the flexibility to solely use newspapers and other print media under certain circumstances such as in areas with limited broadband internet access, in areas with NPDES-regulated entities owned or operated by identifiable populations (*e.g.*, Amish, Mennonite, and Hutterite) who do not use certain technologies (*e.g.*, computers or electricity), and during large-scale disasters (*e.g.*, hurricanes) or prolonged electrical system outrages. Providing the permitting authority with the flexibility to phase in use of their public Web sites, as well as the ability to opt out of its use under certain circumstances, would be consistent with EPA's approach to required electronic reporting of NPDES information in its NPDES Electronic Reporting Rule in Part 127. Requiring permitting authorities to use their publicly available Web site to post all NPDES permit and hearing information could help advance EPA's commitment in its 2009 Clean Water Act Enforcement Action Plan and in its NPDES Electronic Reporting Rule to improve and enhance public access to information.

EPA is also seeking comment on whether proposed revisions to public notice requirements in 40 CFR 124.10(c) should be expanded to include NPDES non-major individual and general permits. This would increase public access to permit and hearing information on the entire NPDES-permitted universe.

In addition, EPA is seeking comments on ways in which NPDES permits and fact sheets could be posted electronically to make it easier for EPA's Enforcement and Compliance History Online (ECHO) information system to link to the permit fact sheets (*e.g.*, one state posts NPDES permits on its Web site by embedding the NPDES identification number into the URL).

Given the wide availability of the internet, it is EPA's view that publication through such means would be effective in informing the public of all such permit applications and hearings.[27] EPA is proposing that where the permitting authority opts to post this information on the Web site in lieu of newspaper publication, it must post all notices to its Web site to maintain one repository of public notice documents. EPA seeks comment on its proposal to require a permitting authority to post all notices on its Web site if it seeks to use its Web site in lieu of a newspaper notice for permit-related information.

A permitting authority that uses the web in lieu of a newspaper to post notices could realize significant financial savings and post more information over a longer period of time, fostering greater public access to information and greatly reducing state burden with regard to public notice. Providing the draft permit and fact sheet during the full public comment period and making the final permit electronically available over the lifetime of the permit can significantly increase the public's access to permitting information compared to the single-day newspaper notice and access to paper copies of the permit at the agency's office.

EPA has carefully evaluated the potential effect of this proposed revision on underserved communities with environmental justice (EJ) concerns. EPA consulted a recent study conducted by Native Public Media that found that the primary source for national and international news among Native American tribes is the internet.[28] Newspapers were listed as only the third most commonly used source for news. EPA also consulted the recently finalized National Environmental Justice Advisory Council (NEJAC), EJ in Permitting Subgroup Report.[29] The report states that "[n]otification of the public by publishing in the legal section of regional newspapers is antiquated and ineffective. This method should not be counted on to communicate, even if legally required."[30] The NEJAC specifically listed Web site postings as a method to ensure meaningful public participation. Thus, based on the EJ in Permitting Subgroup Report's results, EPA concludes that notice via the internet would be a viable and effective means of making information widely available to the public. Permitting authorities are encouraged to provide additional notice where the Director determines that a specific jurisdiction or population would be better served with notice by means of the internet or a newspaper.

EPA seeks comments on both the proposed revision and on the possible alternative option described.

2. CWA Section 401 Certification Process (40 CFR 124.55(b))

40 CFR 124.55(b) addresses the circumstances under which a state may issue a modified CWA section 401 certification in connection with an EPA-issued NPDES permit and the effect of a modified section 401 certification on such a permit. Pursuant to this regulation, if a court of competent jurisdiction or an appropriate state board or agency invalidates a certification condition after final agency action on the permit, EPA can modify such permits only to delete state certification conditions upon request of the permittee. Under the current rule, EPA cannot modify already-issued permits to reflect state court, board or agency decisions that would require the state certifications (and arguably the federal permits subject to that certification) to include more stringent provisions.

The proposed revisions to 40 CFR 124.55(b) would broaden the circumstances under which federal NPDES permits can be modified after issuance to include the addition of permit conditions based on more stringent section 401 certification provisions that result from state administrative or judicial decisions.

Such permit modifications may be requested by anyone and not just the permittee. This change would recognize the importance of state administrative and judicial review process for CWA section 401 certifications by allowing decisions made by state administrative bodies and courts regarding challenges to state certification conditions to be fully reflected in the federal permit, even after the permit is issued. If, upon review, a state administrative body or court determines that more stringent section 401 certification conditions are necessary to adequately protect water quality or to be consistent with state laws, EPA would have the discretion to modify already-issued federal permits to include those more stringent conditions. It is EPA's view that its current ability to only delete section 401 certification-based permit conditions hinders its ability to ensure that permits are environmentally protective and that they reflect the most up-to-date state administrative and judicial determinations. EPA is not able to estimate the number of state administrative or judicial determinations there may be that determine that more stringent conditions are necessary. EPA therefore cannot predict how often this proposed provision may be used. However, it is EPA's view that even if used rarely, this provision would be an important tool for EPA to be able to modify its permits in order to implement limits that better protect water quality.

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[27] Courts have consistently recognized that the critical aspect of public notice is not the particular means of giving notice, but rather that the selected method is reasonably calculated to provide that notice. In discussing service of process by email, the 9th Circuit Court has described in broad language a court's authority to adapt its procedures to meet technological advances as follows: "In proper circumstances, this broad constitutional principle [*i.e.*, that the selected method of service must be reasonably calculated to provide notice and an opportunity to respond] unshackles the Federal courts from anachronistic methods of service and permits them entry into the technological renaissance." *Rio Properties, Inc.* v. *Rio International Interlink*, 284 F.3d 1007, 1017 (9th Cir. 2002).

[28] Morris, Traci L, and Sascha D. Meinrath. "New Media, Technology and Internet Use in Indian Country" Native Public Media, available at *http://www.atalm.org/sites/default/files/NPM-NAF_New_Media_Study_2009_small.pdf.*

[29] See, "Enhancing Environmental Justice in EPA Permitting Program." National Environmental Justice Advisory Council. April, 2011, available at *http://www3.epa.gov/environmentaljustice/resources/publications/nejac/ej-in-permitting-report-2011.pdf*

[30] Id., p.20.

EPA seeks comments on this proposed revision, including comments that estimate how often this provision may be used and on any anticipated impacts.

3. Fact Sheet Requirements (40 CFR 124.56)

EPA proposes to revise 40 CFR 124.56 to require specific documentation in the fact sheet developed to support an individual or general permit. Fact sheets, required for major NPDES permits and general permits per 40 CFR 124.8, "sets forth the principal facts and the significant factual, legal, methodological, and policy questions considered in preparing the draft permit." NPDES PWM, 11.2.2. The existing regulations at 40 CFR 124.56 contain basic requirements for information that must be presented in a fact sheet. It is EPA's view that more precisely outlining the required fact sheet information would result in more comprehensive and focused fact sheets, and correspondingly, would facilitate more efficient, transparent and effective documentation of permitting decisions.

The proposed revisions to 40 CFR 124.56(a) are in two parts—one part for individual permits and one part for general permits. This accommodates differences in the information that permit writers use to develop effluent limits and conditions for individual facilities versus the information used to develop effluent limits and conditions for multiple facilities covered under one general permit.

EPA specifically seeks comments on proposed revisions to fact sheet requirements, as described below.

(a) 40 CFR 124.56 Revisions to Fact Sheet Contents

40 CFR 124.56(a)

An NPDES permit is developed based on careful consideration of existing data and available information relevant to the potential discharge. While the permit itself contains the terms and conditions required of the permittee, the rationale and basis for the decisions made in developing those terms and conditions are contained within the fact sheet and administrative record for that permit. The existing regulations at 40 CFR 124.56 contain basic requirements for information that must be presented in a fact sheet.

However, EPA reviews of state-issued NPDES permits within the past ten years have identified widespread deficiencies in state fact sheet quality. Many fact sheets do not meet the requirements of the existing regulations. Currently, many fact sheets omit critical information regarding limitation development, such as available water quality data, impairment status, existence and implementation of TMDLs and implementation of antidegradation policies. Furthermore, while the existing regulation at 40 CFR 124.56(a) requires fact sheets to generally include "calculations and other necessary explanation," it does not explicitly identify what is required in terms of "calculations" or "other necessary explanation." Fact sheet quality and clarity affects permittees' and the public's ability to meaningfully participate in the permitting process. It is EPA's view that the public and permit applicants should have access to a clear and transparent record of the permit decision making process. By clearly explaining what the 40 CFR 124.56(a) "calculations and other necessary explanations" requirement means, this proposed revision would enable all NPDES permitting authorities to know precisely the kind of thorough and transparent explanations fact sheets should contain to create this clear record. EPA also expects that these clarifications will enable permittees and other members of the public to more easily understand the permit limit development record.

Where the proposed regulation requires an "explanation," "information sufficient," "discussion" or a "description," the proposed language in 40 CFR 124.56(a) allows the fact sheet to include a brief summary of the required information along with a specific reference to the source document in the administrative record. This would relieve the permitting authority from repeatedly providing this information. EPA is clarifying, however, that where the proposed regulations require a "citation" or "identification," a summary would be inappropriate and the fact sheet would need to provide the specific information required. It is EPA's view that this would eliminate redundancy, reduce permit writer workload in fact sheet development, and ensure that the permitting authority is clearly demonstrating and making available all required information. The proposed changes to the regulations would address observed deficiencies and explicitly require fact sheets to include the information necessary to understand the rationale behind permit development.

(b) Fact Sheet Requirements for Individual NPDES Permits

The existing regulations at 40 CFR 124.56 provide basic fact sheet requirements for NPDES permits. While the regulations provide the requirements for content of these fact sheets, they lack specificity, which has led to fact sheets with very little or inconsistent justification of the permit terms and conditions. The proposed regulations would provide specific requirements for both individual and general permits, to provide permit writers with more detail on what information to include in fact sheets.

i. 40 CFR 124.56(a)(1)(i)

The current fact sheet regulation at 40 CFR 124.56(a) requires "a citation to the applicable effluent limitation guideline (ELG), performance standard, or standard for sewage sludge use or disposal as required by 40 CFR 122.44." EPA proposes to redesignate this provision for citations from the existing paragraph (a) as proposed paragraph (a)(1)(i) to allow the inclusion of additional provisions in paragraph (a) in a logical manner.

ii. 40 CFR 124.56(a)(1)(ii)

40 CFR 124.56(a) currently requires fact sheets to include "any calculations or other necessary explanation of the derivation of specific effluent limitations and conditions or standards." The current regulations do not provide any further clarification regarding what constitutes "calculations or other necessary explanation."

The proposed paragraphs (ii)(A) and (ii)(B) would require the fact sheet to contain the name of the receiving water and include explicit reference to the applicable state WQS. EPA intends to provide information to the public and the permittee on designated uses of the receiving water(s) and to provide a clear reference to the applicable numeric and narrative criteria for the specific receiving water segment. In order to write WQBELs, permit writers must already consider the receiving water and applicable state WQS, and already has this information available. Explicitly documenting this known information in a fact sheet would add only a minimal burden, and the permit writer would not have any additional burden of obtaining new information.

The proposed paragraphs (ii)(C) and (ii)(D) would require the fact sheet to include information regarding the condition of the receiving water(s), including whether the water body has been listed as impaired or threatened for any uses. Where the water body is impaired, the fact sheet must indicate whether EPA has approved or established a TMDL for any of the impairing pollutants or pollutant parameters. This requirement is intended to ensure that the permitting authority has considered the condition of the receiving water as part of the permit development process and provides additional transparency regarding the rationale for permit conditions. When developing WQBELs, permit writers are already required to consider the condition of the receiving water(s), any impairments, and whether there is a TMDL for the receiving water. Because the permit writer already has this information available, it should add only a minimal burden to document this information in a permit fact sheet.

iii. 40 CFR 124.56(a)(1)(iii)

The proposed paragraph (iii) would require the fact sheet to include the rationale for TBELs developed pursuant to 40 CFR 122.44(a), and an explanation of any best management practices (BMPs) required pursuant to 40 CFR 122.44(k). This explanation should include a discussion of whether any ELGs apply to the facility, and if so, which performance standard(s) (*e.g.,* best practicable control technology currently available (BPT), best available technology economically achievable (BAT), best conventional pollutant control technology (BCT), or new source performance standard (NSPS)) apply to the facility's discharge. The permit writer would already have all of the required information regarding ELGs, performance standards, technology, and BMPs that he or she used to develop TBELs. There would be no additional burden to obtain any new information, and only a minimal burden to document the analyses that the permit writer has already conducted.

iv. 40 CFR 124.56(a)(1)(iv)

The proposed paragraph (iv) would require documentation of the reasonable potential determination, and, where necessary, the development of WQBELs pursuant to 40 CFR 122.44(d).

The proposed paragraph (iv)(A) would require the fact sheet to describe the pollutants or pollutant parameters analyzed in order to determine a need for WQBELs. EPA's review of state-issued permits has found that even where fact sheets contained reasonable potential determinations and WQBEL calculations, they frequently contain little discussion or demonstration regarding how the permitting authority established the "pollutants of concern" list. EPA is proposing this new paragraph to ensure that the permitting authority considers and clearly identifies "pollutants of concern" for the purposes of water quality analyses, and provides a rationale for the decision reached. Permit writers already have the information that they use to identify pollutants of concern, complete a reasonable potential analysis and develop WQBELs, so this proposed revision would not impose any additional burden of collecting new information. It should be only a minimal additional burden for a permit writer to document the calculations and analyses that he or she has already conducted.

The proposed paragraph (iv)(B) would require the fact sheet to provide the ambient (receiving water) pollutant concentration data, or an explanation of why such data is not applicable or available, for pollutants granted a dilution or mixing allowance pursuant to 40 CFR 122.44(d)(1)(ii). The "background" concentration of a pollutant in the receiving water is a critical factor in determining the assimilative capacity of the receiving water. EPA's review of state-issued permits conducted over the past ten years found that fact sheets contained little information regarding background pollutant data, and little explanation regarding how permitting authorities used or did not use background data in limit calculations. This proposed requirement is intended to provide additional transparency with respect to the use of ambient pollutant concentration data in water quality assessments, reasonable potential determinations and permit limit calculations. In order to write permit limits, the permit writer would have already considered background pollutant data, so this proposed revision would not impose any additional information collection burden, and would only impose a minimal burden for documenting analyses that the permit writer has already conducted.

The proposed paragraph (iv)(C) would require that the fact sheet discuss any dilution or mixing considered in water quality evaluations or permit limit development, and where dilution or mixing were considered, how ambient (background) pollutant concentrations were considered in the water quality assessment. This requirement relates to the proposed requirement in paragraph (iv)(B) and is intended to ensure that the permitting authority has considered and justified the appropriateness of any dilution or mixing allowance consistent with provisions of state WQSs. In order to determine a mixing zone or dilution analysis, the permit writer would have already considered background pollutant data. This proposed revision would not impose any additional information collection burden, and would only impose a minimal burden for documenting analyses that the permit writer has already conducted.

The proposed paragraph (iv)(D) would require that where an EPA-approved or established TMDL has assigned a WLA to the point source, the fact sheet must describe how the permit incorporates limits and permit conditions consistent with the assumptions of any WLA assigned to the applicant/permittee discharge. This requirement is based on findings from both EPA's review of state-issued permits and a 2007 Office of Inspector General (OIG) report[31] that found limited documentation in permits to demonstrate the implementation of WLAs from approved TMDLs. In order to write permit limits that comply with 40 CFR 122.44(d)(1)(vii)(B), permit writers should already have considered information from applicable TMDLs and the assumptions of any WLAs. This proposed revision would not impose any burden on the permit writer to obtain new information and may impose only a minimal burden for documenting the analysis the permit writer would have already conducted.

The proposed paragraph (iv)(E) would require the fact sheet to provide a description of how the permit ensures compliance with applicable state narrative water quality criteria and standards, where a reasonable potential determination has been made for an excursion of narrative water quality criterion. The regulations at 40 CFR 122.44(d)(1) specifically require permits to include limits and conditions that achieve WQS, including any state narrative criteria for water quality. EPA's review of state-issued permits related to the surface coal mining sector as well as other reviews of state-issued permits informed EPA that fact sheets rarely discuss whether or how the permitting authority has assessed the need for, or developed, WQBELs or other permit conditions to ensure compliance with narrative criteria. Permit administrative records are also unclear regarding how narrative criteria related to nutrients are assessed and implemented. EPA is proposing this new requirement to ensure that permitting authorities have considered narrative criteria during the permit development process and have documented how these criteria are implemented in the NPDES permit. In order to develop WQBELs, permit writers are already required to consider state narrative water quality criteria and standards and to conduct a reasonable potential analysis. This proposed revision would not impose any additional burden on the permit writer to obtain new information, and may impose only a minimal burden for documenting analyses that the permit writer has already conducted.

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[31] Office of Inspector General, "Total Maximum Daily Load Program Needs Better Data and Measures to Demonstrate Environmental Results." September 19, 2007, available at *http://www.epa.gov/sites/production/files/2015-11/documents/20070919-2007-p-00036.pdf.*

v. 40 CFR 124.56(a)(1)(v)

Fact sheets frequently do not adequately document the antidegradation analysis to ensure that the permitting authority is meeting requirements to protect existing uses and high quality waters (where applicable). In particular, fact sheets often omit information regarding whether the permitting authority conducted a "Tier 2" review consistent with the state's antidegradation requirements in order to demonstrate that allowing a lowering of water quality was consistent with the state's antidegradation requirements. Numerous state NPDES permit challenges have raised this issue. The proposed language would ensure that the permitting authority has considered the applicable antidegradation requirements and has documented that the state's antidegradation requirements are met (*e.g.,* by documenting a Tier 2 review, if applicable). The proposed paragraph (v) would require that the fact sheet contain sufficient information to demonstrate that the proposed discharge is consistent with the state's antidegradation requirements. In order to develop WQBELs, permit writers must already take state WQS into account. State antidegradation policies and requirements are a component of state WQS. This proposed revision would not impose any additional requirements on permit writers to collect new information or conduct new analyses. It may impose only a minimal burden for documenting analyses that permit writers have already conducted.

vi. 40 CFR 124.56(a)(1)(vi)

(c) EPA's review of state practices and policy has shown that the determination of monitoring location(s), the frequency at which the permit requires the permittee to sample and analyze each regulated pollutant, the sampling technique (*e.g.,* grab, composite, continuous), and the required analytical methods are all often carried forward from permit to permit with little or no explanation as to their basis or appropriateness. Further, the NPDES permitting regulations at 40 CFR 122.44(i) were revised in 2014 and now require permitting authorities to prescribe (where necessary) an analytical method that is "sufficiently sensitive" to assess compliance with applicable effluent limitations. The proposed paragraph (vi) would require the fact sheet to discuss the proposed monitoring and reporting conditions of a draft NPDES permit that current fact sheet regulations do not currently specifically address, including assurance that the prescribed analytical methods meet the requirements of 40 CFR 122.44(i). Permit writers already have the data that they use to establish monitoring and reporting requirements and ensure that they are prescribing sufficiently sensitive methods are prescribed. This proposed revision would not impose any additional burden on permit writers to collect new information or conduct new analyses. It may impose only a minimal burden for documenting analyses that permit writers have already conducted.

(d) Fact Sheet Requirements for NPDES General Permits

While current fact sheet regulations at 40 CFR 124.8(a) require development of fact sheets for draft NPDES general permits, the regulations at 40 CFR 124.56 do not include requirements specific to the contents of fact sheets for these permits. General permits are "umbrella" permits that cover classes or categories of dischargers, and are usually used when there are multiple facilities that have very similar discharges. General permits are an efficient tool used by permitting authorities to provide permit coverage for many facilities under just one permit. Fact sheets for general permits are especially essential in providing the rationale for the development of terms and conditions for general permits and provide applicants and the public with background and information on how the limits, terms and conditions in the permit were developed. Because of the unique nature of general permits, EPA believes that the regulations should describe the specific fact sheet requirements that more accurately describe and document the development of the terms and conditions of general permits.

EPA proposes the following new 40 CFR 124.56(a)(2) to address the specific information necessary to document permitting decisions for NPDES general permits. The proposed general permit fact sheet requirements closely track the general permit structure in 40 CFR 122.28.

i. 40 CFR 124.56(a)(2)(i)

Proposed paragraph (a)(2)(i) would require the fact sheet for a general permit to contain a description of how the issuance of the general permit meets the requirements of 40 CFR 122.28, including the geographic area of coverage: The types, classes or categories of waters to which the general permit authorizes discharge and the sources that the general permit would cover. This information would ensure that the permitting authority provides a transparent record of the types of facilities covered under the general permit and the criteria under which categories or classes of facilities were identified. Furthermore, the fact sheet would be specifically required to provide a record of decision for selecting the geographic area of coverage, including any areas or water bodies where general permit coverage is not available. In order to develop a general permit, permit writers will have already considered all of the relevant data regarding the geographic area of coverage and the kinds of facilities and discharges that the general permit covers. This proposed revision would impose no new burden on permit writers to obtain new information or conduct new analyses. It may impose only a minimal burden to document the analyses that permit writers have already conducted.

ii. 40 CFR 124.56(a)(2)(ii)

The current fact sheet regulation requires "a citation to the applicable effluent limitation guideline, performance standard, or standard for sewage sludge use or disposal as required by § 122.44." The proposed paragraph moves the original language into paragraph 124.56(a)(2)(ii) and would not substantively change the existing requirement.

iii. 40 CFR 124.56(a)(2)(iii)

The proposed paragraph (iii) requires that the fact sheet provide the rationale for TBELs developed pursuant to 40 CFR 122.44(a), and an explanation of any BMPs required pursuant to 40 CFR 122.44(k). This explanation would include a discussion of whether any ELGs apply to the facility, and if so, which performance standard(s) (*e.g.,* BPT, BAT, BCT, NSPS) apply to the facility's discharge. The permit writer would already have all of the required information regarding ELGs, performance standards, technology, and BMPs that he or she used to develop TBELs. There would be no additional burden to obtain any new information, and only a minimal burden to document the analyses that the permit writer has already conducted.

iv. 40 CFR 124.56(a)(2)(iv)

The proposed paragraph (iv) deals with documentation of the reasonable potential determination and, where necessary, the development of WQBELs or conditions. Because general permits cover facilities that may be widely dispersed across multiple water bodies and watersheds, the water quality analysis would likely differ significantly from the site-specific type of analysis performed for an individual discharger. Therefore, fact sheet requirements must account for the unique approaches taken in general permits to ensure compliance with state WQS. However, while the approaches and rationales may differ, paragraph (iv) would require that the fact sheet provide a rationale that describes how the permit will ensure compliance with state WQS, which includes consideration of applicable state antidegradation policies and applicable WLAs from EPA-approved or established TMDLs. In order to develop WQBELs for general permits that ensure compliance with state WQS, permit writers will have already considered relevant analytical data pertaining to WQS (including antidegradation policies and requirements) and TMDLs. This proposed revision would not impose an additional burden on permit writers to collect any new data or perform additional analyses, and may impose only a minimal burden for the permit writer to document the analyses he or she has already conducted.

v. 40 CFR 124.56(a)(2)(v)

The proposed paragraph (v) addresses documentation of monitoring and reporting provisions of a draft NPDES general permit that current fact sheet regulations do not currently specifically address. Based on past practices and state policy, determination of monitoring location(s), the frequency at which the permit requires the permittee to sample and analyze each regulated pollutant, the sampling technique (*e.g.*, grab, composite, continuous) and the required analytical methods are all often carried forward from permit to permit. Further, the NPDES permitting regulations at 40 CFR 122.44(i) were revised in 2014 and now require permitting authorities to prescribe (where necessary) an analytical method that is "sufficiently sensitive" to assess compliance with applicable effluent limitations. The proposed paragraph (v) would require that the fact sheet provide a discussion of proposed monitoring and reporting conditions, including assurance that prescribed analytical methods meet the requirements of 40 CFR 122.44(i). Permit writers already have the data that they use to establish monitoring and reporting requirements and ensure that they are prescribing sufficiently sensitive methods are prescribed. This proposed revision would not impose any additional burden on permit writers to collect new information or conduct new analyses. It may impose only a minimal burden for documenting analyses that permit writers have already conducted.

vi. 40 CFR 124.56(a)(2)(vi)

The proposed paragraph (vi) would require that the fact sheet provide an explanation of the administrative elements of the general permit, including the process by which a facility would seek and be granted coverage under the general permit. Where the general permit does not require a NOI, the fact sheet must also provide a description of why the NOI process is inappropriate in accordance with the criteria established in 40 CFR 122.28(b)(2)(v). Permit writers already include NOI provisions in general permits, so documenting these processes in fact sheets would not impose an additional burden on permit writers to develop a new process, and may impose only a minimal burden to document this process in the fact sheet.

EPA Requests comments on the proposed revisions to § 124.56(a).

(e) Other Revisions to 40 CFR 124.56

i. 40 CFR 124.56(b)(1)(vii)

40 CFR 124.56(b)(1) mandates an explanation of why a draft permit includes particular conditions. The proposed rule would include a requirement to provide a rationale for the use of compliance schedules in fact sheets for draft NPDES permits. In 2007, EPA addressed concerns over the use of compliance schedules in draft permits through a memorandum titled, "Compliance Schedules for Water Quality-Based Effluent Limitations in NPDES Permits" from James A. Hanlon, Director of EPA's Office of Wastewater Management, to Alexis Strauss, Water Division Director of EPA Region 9.[32] The memorandum clarifies, "[w]hat principles are applicable to assessing whether a compliance schedule for achieving a water quality-based effluent limitation is consistent with the CWA and its implementing regulations." Paragraph (b)(1)(vii) of the proposed regulatory revision requires the draft permit fact sheet to contain an explanation and justification for the use of a compliance schedule in any draft NPDES permit. The appropriateness of a compliance schedule is a permit-specific determination. The NPDES regulations at 40 CFR 122.47 contain requirements for compliance schedules. The intent of this new provision is to ensure that the permitting authority has considered the appropriateness of the compliance schedule in light of the criteria established in the regulations at 40 CFR 122.47 and described in the 2007 EPA memorandum, and has documented these decisions in the fact sheet. If a permit contains a compliance schedule, permit writers should have already considered whether the compliance schedule meets the requirements of 40 CFR 122.47. This proposed revision would not impose a new burden on permit writers to collect new data or perform new analyses, and may impose only minimal burden on permit writers to document analyses that they have already conducted.

ii. 40 CFR 124.56(c)

The current provisions of paragraph (c) require, when appropriate, a sketch or detailed description of the location of the discharge or regulated activity. The proposed rule would add to this paragraph a requirement that the fact sheet provide geographic coordinates (*e.g.*, latitude and longitude) for each discharge or regulated activity. This locational information is already required to be provided by the applicant for an NPDES permit through its individual permit application. 40 CFR 122.21. Including this information as part of the fact sheet would provide the public with better information regarding the precise location of the regulated activity and would facilitate the use of internet-based geo-locational tools.

With respect to NPDES general permits, locational information is generally provided through the Notice of Intent (NOI) submitted by a facility after issuance of the general permit. The fact sheet for the general permit would include a description of the geographic area within which facilities may seek coverage under the general permit. This is consistent with the existing requirement in 40 CFR 122.28(a)(1) which requires the general permit to establish the geographical "area" within which coverage under the general permit may be sought.

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[32] James Hanlon. "Compliance Schedules for Water Quality-Based Effluent Limitations in NPDES Permits" May 10, 2007, available at *http://www3.epa.gov/npdes/pubs/memo_complianceschedules_may07.pdf.*

This revision would not increase the level of effort for permittees and would not alter the requirements for data submission as part of the permit application process. The changes also would not alter the current substantive requirements for developing NPDES permits, but rather would more clearly specify the information required for the documentation of how those requirements were developed.

EPA seeks comments on the proposed revisions to 40 CFR 124.56(b) and (c).

D. Proposed Revision to 40 CFR Part 125

1. Deletion of 40 CFR 125.3(a)(1)(ii)

EPA proposes to delete 40 CFR 125.3(a)(1)(ii) from the NPDES regulations. The statutory authority supporting this provision was repealed in 1981 making this requirement no longer applicable to POTWs covered under NPDES permits. Public Law 97–117. Therefore, EPA proposes to remove this provision from the regulations in order to avoid confusion regarding its applicability.

Since EPA is removing language to be consistent with repealed statutory language, EPA is not seeking comments on the proposed removal or on the existing regulation.

IV. Impacts

This proposal involves numerous revisions to the NPDES regulations. It is EPA's view that these revisions would generally not result in a new or increased impacts or information collection by authorized states or the regulated community. EPA expects that any additional effort for documenting existing analyses and calculations would be minimal. It is also EPA's view that in some cases, these proposed revisions could reduce burden: Deleting outdated information and requirements could make it easier for the public to understand which NPDES regulations apply. The impacts assessment is provided for each topic. EPA specifically requests comments on the impacts and estimated level of effort resulting from the totality of this proposal as well as the individual requirements of the proposal.

In general, revisions may result in a state having to make statutory or regulatory revisions in order to maintain a program that is at least as stringent as the federal program. Existing Information Collection Requests (ICRs) related to the NPDES regulations account for program revisions where they are necessary because the controlling federal statutes or regulations were modified. This proposal does not impose any changes to the procedures for revising state programs at 40 CFR 123.62 and it would not result in a new or increased effort beyond what has already been accounted for in the existing ICRs.

Purpose and Scope of the NPDES Program (40 CFR 122.1)

The revision to this note is being made to inform the public of ways to contact the NPDES program and would not result in changes to the existing program or program requirements. The note in the existing regulation contains an outdated address and telephone number for the Office of Water. Providing updated information will save the permitting authorities and the public time when they seek to contact EPA about these regulations.

NPDES Program Definitions: Pesticide Applications to Waters of the United States, New Discharger, Proposed Permit, and Whole Effluent Toxicity Definition (40 CFR 122.2)

The proposed revisions to the NPDES program definitions at 40 CFR 122.2 for "pesticide applications to waters of the United States," "new discharger," "proposed permit" and "whole effluent toxicity" would not result in an increase in effort or information collection. These revisions are being made to improve programmatic clarity and would not result in substantive changes to the existing program or program requirements.

Adding a definition of "pesticide applications to waters of the United States" brings the NPDES definitions into concert with the way the PGP has been interpreting and regulating such applications since 2011. This definition would not increase burden and would not expand the universe of permittees and activities that the PGP covers.

EPA proposes correcting a typographical error in subsection (d) of this definition by changing "NDPES" to "NPDES." This will not increase burden and will enable the public to clearly understand EPA's regulations.

It is EPA's view that the revised definition of "proposed permit" also would not add any burden. This definition would correlate with the changes EPA proposes regarding objection to administratively continued permits. EPA proposes that an administratively continued permit could be designated as "proposed" after either a two-year or five-year period following the initial five-year permit term. Under the proposed revisions, EPA could then object to these proposed permits according to the existing permit objection regulations at 40 CFR 123.44. Although this revised definition could increase the number of permits to which EPA could object, EPA does not anticipate that this revised definition would increase burden for states, permittees, or any other stakeholders. Permittees will have already submitted the required permit renewal applications in a timely manner. After EPA designates an expired, administratively continued permit as a "proposed permit," the state NPDES permitting authority can choose to issue its own new draft permit based on the permittee's timely application, and the state permitting process would proceed as usual. If the state permitting authority were to choose not to issue its own new draft permit, EPA could issue the permit and would assume any additional workload.

The revised definition of WET would reflect current implementation practice and would impose no additional burden. The revised definition would clarify that WET includes both acute (lethal) and chronic (lethal and sublethal) WET test endpoints. As discussed in section III of this preamble, this clarification would be consistent with EPA's existing WET interpretation and implementation. Clarifying this definition would not change the existing requirement that NPDES permits include WET limits where necessary to meet state numeric and narrative water quality aquatic life protection criteria. 40 CFR 122.44(d)(1)(iv) and (v).

Vessels Exclusion (40 CFR 122.3(a))

The proposed revision to 40 CFR 122.3(a) to remove an outdated provision related to vessel discharges would not result in an increase in effort or information collection. This proposed revision would incorporate or otherwise address CWA provisions that were enacted after the current regulations were promulgated as well as a judicial decision vacating the 40 CFR 122.3(a) exclusion for discharges incidental to the normal operation of a vessel from NPDES permitting. As a result, this proposed revision would not result in a new or increased effort and would not change the universe of permittees covered by the existing VGP.

Application Requirements (40 CFR 122.21)

The proposed revision to 40 CFR 122.21 related to updates and clarifications to the existing application requirements and corresponding forms would not result in an increase in effort or information collection. EPA is revising several data fields to refine the content and improve the consistency among the forms, to improve the consistency with EPA's current data standards, and improve the clarity and usability of the forms. It is EPA's view that the new application forms would be easier to use and understand, and may result in a decrease in effort for permittees applying for coverage. EPA also expects that the revisions would improve the quality of information being collected, which may reduce the need for follow-up questions and data requests, and the time necessary for the state to develop a permit.

In 2008, EPA submitted an ICR to the Office of Management and Budget (OMB) that, in part, updated EPA's estimates for applicants to complete Forms 1, 2A, 2C–2F, and 2S and for permitting authorities to review applications for point source and sewage sludge management permits.[33] The renewal ICR did not include updated estimates for Form 2B or for forms associated with cooling water intake structures (item 8 in table IV–1). Updated estimates to complete those forms were contained in separate ICRs.[34] The existing ICRs include annual estimates for completing NPDES permit applications and for conducting ongoing compliance monitoring for both new and existing NPDES permittees.

In the final rule, EPA will submit to OMB an updated ICR that describes the estimated effort associated with the proposed revisions made to the application regulations and forms. The changes proposed in this rule are minor, and do not change the estimated burden for completing the forms established in the existing ICRs.

Antidegradation Reference (40 CFR 122.44(d))

The proposed revision to 40 CFR 122.44(d) would include a reference to 40 CFR 131.12 in order to ensure consistency with the state antidegradation requirements established under that section and would not result in an increase in level of effort or information collection. This addition clarifies that permitting authorities should use applicable antidegradation requirements when deriving WQBELs. All state water quality standards include antidegradation policies. EPA's longstanding policy has been that permitting authorities should develop NPDES permit terms and conditions consistent with, and in consideration of applicable state antidegradation requirements. NPDES permit writers are already required to consider how the final WQBELs established in the permit not only derive from the numeric and narrative water quality criteria, but also how they satisfy the antidegradation elements of state WQS. This would remain the case regardless of whether EPA includes this provision as a reminder. Because the NPDES regulations do not presently explicitly include this requirement, this proposal would revise the regulations at 40 CFR 122.44(d)(1) to explicitly clarify this existing assumption. This proposed revision would not result in a new or increased effort.

Dilution Allowances (40 CFR 122.44(d))

The proposed revisions to 40 CFR 122.44(d) specify that a dilution allowance under this paragraph must comply with applicable dilution and mixing zone requirements and low flows established in state WQS and be supported by data or analyses quantifying or accounting for the presence of each assessed pollutant or pollutant parameter in the receiving water. This proposal would not require collecting new information or conducting any new calculations, but rather is intended to ensure transparency in the permitting authority's decision to grant a dilution allowance. The information necessary to support a dilution allowance may be based on existing information, or the permitting authority may choose to ask the applicant seeking coverage for more information. This proposed revision would not require new or increased effort or costs.

Reasonable Potential Determinations for New Discharges (40 CFR 122.44(d))

The proposed revision to 40 CFR 122.44(d) specifies that a reasonable potential determination must consider applicable qualitative or quantitative data, analyses or other valid and representative information for pollutants or pollutant parameters to support the need for effluent limitations, conditions or standards. This proposal does not require collecting new information, but rather is intended to ensure that the permitting authority uses all available information when determining the need for an effluent limitation for a new discharge. In addition, the revision ensures that the permitting authority is transparent regarding the process used to make the determination by including documentation in the permit fact sheet. This proposed revision would not result in a new or increased effort.

Anti-Backsliding (40 CFR 122.44(l))

The proposed revision to 40 CFR 122.44(l) to be consistent with CWA section 402(o) provisions regarding "anti-backsliding" from permit limitations would not result in an increase in effort or information collection. This revision would incorporate the existing statutory requirement into the regulations verbatim and would not create any new requirements or information collection burdens.

Design Flow for POTWs (40 CFR 122.45(b))

The proposed revision to 40 CFR 122.45(b) would clarify that permit effluent limitations based on technology standards for POTWs must be calculated using design flow. This revision also clarifies that the permitting authority has the flexibility to use other appropriate measures of a representative critical condition when developing effluent limitations based on WQS for a POTW. A WQBEL for a POTW could instead be based on effluent flows other than design flow (*e.g.,* actual flow, estimated flow). EPA proposes to clarify that permitting authorities developing WQBELs for POTWs have the same flexibility to base calculations on effluent flows as they do for the development of WQBELs for all other dischargers. This proposal would not impose any additional burden or require any additional calculations.

Objection to Administratively Continued Permits (40 CFR 123.44)

The proposed revision to 40 CFR 123.44 to allow EPA to review an administratively continued permit as a proposed permit for the purposes of making an objection determination would not result in an increase in effort or information collection. The proposal would not change the existing timeframes established in the permit objection regulations and would not require any new information to be submitted to EPA as a part of the process. It also would not impose additional burdens on authorized state NPDES programs, who have the responsibility to timely issue NPDES permits. If EPA were to invoke the authority in this proposed provision, the responsibility to issue the permit could potentially shift to EPA. This proposed revision would not result in a new or increased effort for states. See impacts explanation for "proposed permit" in "Definitions (40 CFR 122.2)" above.

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[33] USEPA. "Information Collection Request (ICR) for National Pollutant Discharge Elimination System (NPDES) Program (Renewal)," OMB Control No. 2040–0004, EPA ICR No. 0229.19, December 2008.

[34] USEPA. "Supporting Statement for the Information Collection Request for the NPDES Regulation and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations," OMB Control No. 2040–0250, EPA ICR No. 1989.04, June 2006.

USEPA, "Information Collection Request (ICR) for Cooling Water Intake Structures at Phase III Facilities (Final Rule)," OMB Control No. 2040–0268, EPA ICR No. 2169.02, February 2009.

USEPA, "Information Collection Request (ICR) for Cooling Water Intake Structures Phase II Existing Facilities (Renewal)," OMB Control No. 2040–0257, EPA ICR No. 2060.03, May 2007.

USEPA, "Information Collection Request (ICR) for Cooling Water Intake Structures New Facility Rule (Renewal)," OMB Control No. 2040–0241, EPA ICR No. 1973.04, June 2008.

Public Notice Requirements (40 CFR 124.10(c))

The proposal to revise 40 CFR 124.10(c) to allow permitting authorities to provide public notice of NPDES major individual and general permits on the permitting authority's publicly available Web site in lieu of the newspaper publication requirement would not result in an increase in effort or information collection. EPA is not proposing to alter the existing requirement related to newspaper publication, but is providing an optional provision that the permitting authority may choose at its discretion. However, to qualify for this provision, the permitting authority would be required to post the draft permit and fact sheet on the Web site during the public comment period and post the final permit and fact sheet for the entire term of the permit. The purpose of this proposed revision is to provide the permitting authority with an alternative method of providing notice of permit applications and hearings and provide flexibility to reach communities in a variety of methods. It is EPA's understanding that the traditional approach to newspaper publication has become costly for permitting authorities to implement. EPA's proposal intends to alleviate those costs by allowing the permitting authority to use its publicly available Web site in lieu of the traditional publication.

EPA estimates that public notice of draft permits in newspapers for NPDES major facilities, sewage sludge facilities and general permits currently costs approximately $1.6 million per year, nationally.[35] This estimate excludes the costs of preparing the content of the NPDES public notice, and the costs of the other methods to provide notice besides newspaper publication, such as direct mailing. Any costs from EPA's proposed rule, however, are likely to be less than this amount. For example, EPA expects that the cost of posting a PDF copy of a public notice on a state's pre-existing NPDES Web site could be less than the cost of publishing such notices in a newspaper. Although EPA does not currently have estimates of those costs, this revision would be a significant decrease in burden for public notice requirements for permitting authorities. The rule would allow but not require state and federal permitting authorities to use electronic public notice instead of newspaper publication. Some states would continue to publish at least some notifications in newspapers.

This proposed revision would not result in an increase in effort or information collection. EPA specifically seeks comments on the potential cost savings for the public notice of NPDES major individual and general permits on a publicly available Web site in lieu of the newspaper publication requirement.

CWA Section 401 Certification Process (40 CFR 124.55(a)(2))

The proposal to revise 40 CFR 124.55(a)(2) would broaden the circumstances under which federal NPDES permits could be modified after issuance to include conditions necessary to reflect more stringent section 401 certification provisions that result from state administrative or judicial decisions. EPA cannot predict how often this proposed provision would cause a permit to be modified. Any modifications resulting from requirements in state administrative or judicial decisions would follow EPA's existing permit modification regulations at 40 CFR 122.62. Any new permit requirements would be the result of an administrative or judicial decision and would not result directly from this proposed revision. Therefore, this proposed revision would not result in an increase in effort or information collection.

Fact Sheet Requirements (40 CFR 124.56)

The proposal to revise 40 CFR 124.56 to require specific documentation within the fact sheet content of the individual and general permit development would not result in an increase in effort or information collection. The proposed changes to the fact sheet content requirements do not establish any permit conditions or technical or administrative analyses that are not already required by the existing regulations. The revised regulations would require the permitting authority to document NPDES permit development work that the existing regulations already require. These proposed revisions would not impose any additional burdens for collecting new data or conducting new analyses, and may impose only a minimal burden for permit writers to document analyses that have already been conducted.

Deletion of 40 CFR 125.3(a)(1)(ii)

The proposed deletion of 40 CFR 125.3(a)(1)(ii) from the NPDES regulations would not result in an increase in effort or information collection. By deleting this outdated provision, EPA would clarify that this provision no longer applies to regulated entities.

V. Compliance Dates

Following issuance of this rule, authorized states have up to one year to revise, as necessary, their NPDES regulations to adopt the requirements of this rule, or two years if statutory changes are needed, as provided at 40 CFR 123.62.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a "significant regulatory action" because it raises novel legal and policy issues. Accordingly, EPA submitted this action to the OMB for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action. Information regarding all statutes and executive orders discussed in this document can be found at *http://www.epa.gov/laws-regulations/laws-and-executive-orders.*

B. Paperwork Reduction Act (PRA)

The changes being proposed to the applications and forms as well as all other information collection activities in this proposed rule will be submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2529.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

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[35] EPA used $1,000 (in 2010$) as the publication cost for a public notice in a newspaper and assumed that there are 1,600 NPDES permit actions that require public notice via newspaper publication each year; thus, we arrive at the $1.6 million per year estimate.

The ICR will describe the burden and costs associated with revisions made to regulations and forms related to preparing and reviewing applications for individual NPDES permits for point source and sewage sludge management permits. These revisions were necessary to clarify NPDES definitions and application requirements, increase fact sheet and permit transparency, timeliness and environmental effectiveness, and modernize public notice methods.

The proposed revisions to 40 CFR 122.21 related to clarifications of NPDES definitions and application requirements would not result in an increase in level of effort or information collection. EPA is making revisions to several data fields on the forms to refine the content and to improve consistency with EPA's current data standards. The application forms is available in the docket for this rule. EPA estimates that the burden associated with these proposed changes would not change from the burden estimates contained in existing ICRs. This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB OMB Control No. 2040–0004, EPA ICR No. 0229.21.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

EPA requests comment on the impact of the specific changes set out in this proposal on NPDES application requirements, forms and other information collections. EPA also requests comment on whether and how a separate future action should address the utility and clarity of the information requests and on how to minimize the information collection burden on respondents, including the use of appropriate automated, electronic, mechanical, or other forms of information technology. Comments relating to this separate future action should be submitted to Docket ID No. EPA–HQ–OW–2016–0146 at *http://www.regulations.gov.*

C. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (RFA). In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. This proposal would eliminate inconsistencies between regulations and application forms, improve permit documentation, transparency and oversight, provide clarifications to existing regulations and delete outdated provisions. We have therefore concluded that this action would have no net regulatory burden for directly regulated small entities.

EPA continues to be interested in the potential impacts of the proposed rule on small entities and welcomes comments on issues related to such impacts.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This proposal would eliminate inconsistencies between regulations and application forms, improve permit documentation, transparency and oversight, provide clarifications to existing regulations and delete outdated provisions. This proposed action will not impose significant burden on EPA, states or the regulated community, or specifically, any significant burden on any small entity. With respect to any impacts on authorized state programs, the costs involved in this action are imposed only by participation in a voluntary federal program. UMRA generally excludes from the definition of "federal intergovernmental mandate" duties that arise from participation in a voluntary federal program. Thus, this proposed rule is not subject to the requirements of section 202 and 205 of the UMRA. For the same reason, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Thus, this proposed rule is not subject to the requirements of section 203 of UMRA.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications, as specified in Executive Order 13175. EPA considered the potential impacts on tribes, and concluded that there would be no substantial direct compliance costs or impact on tribes. Because the purpose of the proposed rule is to eliminate inconsistencies between regulations and application forms, improve permit documentation, transparency and oversight, provide clarifications to existing regulations, and delete outdated provisions, it is not expected to have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175. Executive Order 13175 does not apply to this action and EPA determined that tribal consultation is not necessary for this action.

EPA specifically solicits input on this proposed action from tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The proposed rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866 and because EPA does not believe that the environmental health and safety risks addressed by this action present a disproportionate risk to children. This proposed rule would eliminate inconsistencies between regulations and application forms, improve permit documentation, transparency and oversight, provide clarifications to existing regulations, and delete outdated provisions.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This rulemaking is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This proposed rule would eliminate inconsistencies between regulations and application forms, improve permit documentation, transparency and oversight, provide clarifications to existing regulations, and delete outdated provisions.

I. National Technology Transfer and Advancement Act

This proposed rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low Income Populations

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. This proposed rule would eliminate inconsistencies between regulations and application forms, improve permit documentation, transparency and oversight, provide clarifications to existing regulations and delete outdated provisions.

List of Subjects

40 CFR Part 122

Administrative practice and procedure, Confidential business information, Environmental protection, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 123

Administrative practice and procedure, Confidential business information, Hazardous substances, Indians—lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 124

Administrative practice and procedure, Air pollution control, Hazardous waste, Indians—lands, Reporting and recordkeeping requirements, Water pollution control, Water supply.

40 CFR Part 125

Reporting and recordkeeping requirements, Waste treatment and disposal, Water pollution control.

Dated: May 5, 2016.

Gina McCarthy,

Administrator.

For the reasons set out in the preamble, the EPA proposes to amend Chapter I of Title 40 of the Code of Federal Regulations as follows:

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

■ 1. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 *et seq.*

Subpart A—Definitions and General Program Requirements

■ 2. Section 122.1 is amended by revising the note to § 122.1 to read as follows:

§ 122.1 Purpose and scope.

* * * * *

[**Note to § 122.1:** Information concerning the NPDES program and its regulations can be obtained by contacting the Water Permits Division (4203), Office of Wastewater Management, U.S. EPA, 1200 Pennsylvania Avenue NW., Washington, DC 20460 and by visiting the homepage at *http://www.epa.gov/npdes/.*]

■ 3. Section 122.2 is amended by:

■ a. Revising the definitions for "new discharger," "proposed permit," and "whole effluent toxicity" in paragraph (d); and

■ b. Adding the definition, in alphabetical order, "pesticide applications to waters of the United States."

The revisions and additions read as follows:

§ 122.2 Definitions.

New discharger means any building, structure, facility, or installation:

* * * * *

(d) Which has never received a finally effective NPDES permit for discharges at that "site."

* * * * *

Pesticide applications to waters of the United States means the application of biological pesticides, and the application of chemical pesticides that leave a residue, from point sources to waters of the United States. In the context of this definition of pesticide applications to waters of the U.S., this does not include agricultural stormwater discharges and return flows from irrigated agriculture, which are excluded by law (33 U.S.C. 1342(l)).

* * * * *

Proposed permit means a State NPDES "permit" prepared after the close of the public comment period (and, when applicable, any public hearing and administrative appeals) which is sent to EPA for review before final issuance by the State, or a State NPDES permit designated as a proposed permit under § 123.44(k). A "proposed permit" is not a "draft permit."

* * * * *

Whole effluent toxicity (WET) means the aggregate toxic effect of an effluent measured directly by a toxicity test where the test results are based on acute (lethal) and/or chronic (lethal and sublethal) endpoints.

■ 3. Section 122.3 is amended by revising paragraph (a) to read as follows:

§ 122.3 Exclusions.

* * * * *

(a) Any discharge of sewage from vessels and any effluent from properly functioning marine engines, laundry, shower, and galley sink wastes, or any other discharge incidental to the normal operation of:

(1) A vessel of the Armed Forces within the meaning of section 312 of the CWA; and

(2) A recreational vessel within the meaning of section 502(25) of the CWA. Until December 18, 2017, an NPDES permit is not required for a vessel that is less than 79 feet in length or a fishing vessel as defined in 46 U.S.C. 2101 except for any discharge of ballast water or any discharge in a case in which the Administrator or State, as appropriate, determines that the discharge either contributes to a violation of a water quality standard or poses an unacceptable risk to human health or the environment. None of these exclusions apply to rubbish, trash, garbage, or other such materials discharged overboard; nor to other discharges when the vessel is operating in a capacity other than as a means of transportation such as when used as an energy or mining facility, a storage facility or a seafood processing facility, or when secured to a storage facility or a seafood processing facility, or when secured to the bed of the ocean, contiguous zone or waters of the United States for the purpose of mineral or oil exploration or development.

* * * * *

Subpart B—Permit Application and Special NPDES Program Requirements

■ 4. Section 122.21 is amended by:

■ a. Revising paragraph (a)(2)(i) introductory text;

■ b. Revising paragraph (a)(2)(i)(A);

■ c. Revising paragraph (c)(2)(ii)(B);

■ d. Revising paragraphs (f) introductory text and (f)(2) through (4);

■ e. Adding paragraphs (f)(9) and (10);

■ f. Revising paragraphs (g) introductory text and (g)(1);

■ g. Adding paragraph (g)(7)(ix);

■ h. Revising paragraph (h)(1);

■ i. Revising paragraph (i)(1)(iii);

■ j. Revising paragraphs (j)(1)(i), (j)(1)(ii), and (j)(1)(viii)(D)(*2*) and (*3*);

■ k. Adding paragraph (j)(1)(ix);

■ l. Revising paragraphs (j)(3)(i)(C), (j)(4)(i), (j)(5)(i), (j)(6)(i), (j)(6)(ii) introductory text, (j)(6)(ii)(B), (C), (E) and (G), (j)(8)(ii)(A)(*3*) and (j)(9);

■ m. Revising paragraphs (k) introductory text, (k)(1), and (k)(5)(vi);

■ n. Revising paragraphs (q)(1)(i), (q)(2)(i), (q)(8)(ii)(A), (q)(8)(vi) introductory text and (q)(8)(vi)(A), (q)(9)(iii)(B), (D), and (E), (q)(9)(iv)(A), (q)(10)(ii)(A), (q)(10)(iii)(B) and (q)(10)(iii)(K)(*1*), (q)(11)(ii)(A) and (q)(11)(iii)(B), (q)(12)(i), and (q)(13); and,

■ o. Revising paragraph (r)(3)(ii).

The additions and revisions read as follows:

§ 122.21 Application for a permit (applicable to State programs, see § 123.25).

(a) * * *

(2) * * *

(i) All applicants for EPA-issued permits must submit applications on EPA permit application forms. More than one application form may be required from a facility depending on the number and types of discharges or outfalls found there. Application forms may be obtained by contacting: U.S. EPA, Mail Code 4203M, 1200 Pennsylvania Ave. NW., Washington, DC 20460 or by visiting *http://www.epa.gov/npdes*. Applications for EPA-issued permits must be submitted as follows:

(A) All applicants, other than POTWs, TWTDS, vessels, and pesticide applicators must submit Form 1.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(B) The applicant's name, address, telephone number, electronic mail address and ownership status;

* * * * *

(f) *Information requirements*. All applicants for NPDES permits, other than POTWs, other TWTDS, vessels, and pesticide applicators, must provide the information in paragraphs (f)(1) through (10) of this section to the Director, using the application form provided by the Director. Additional information required of applicants is set forth in paragraphs (g) through (k) and (q) through (r) of this section.

* * * * *

(2) Name, mailing address, and location, including latitude and longitude to the nearest second and method of collection, of the facility for which the application is submitted.

(3) Up to four SIC and NAICS codes that best reflect the principal products or services provided by the facility.

(4) The operator's name, address, telephone number, electronic mail address, ownership status, and status as Federal, State, private, public, or other entity.

* * * * *

(9) An indication of whether the facility uses cooling water and the source of the cooling water. (Facilities that use a cooling water intake structure as described at 40 CFR 125.91 must comply with requirements at 40 CFR 122.21(r)).

(10) An indication of whether the facility is requesting any of the variances at 40 CFR 122.21(m).

(g) *Application requirements for existing manufacturing, commercial, mining, and silvicultural dischargers*. Existing manufacturing, commercial, mining, and silvicultural dischargers applying for NPDES permits, except for those facilities subject to the requirements of § 122.21(h), shall provide the following information to the Director, using application forms provided by the Director.

(1) *Outfall location*. The latitude and longitude to the nearest second, including method of collection, and the name of the receiving water.

* * * * *

(7) * * *

(ix) Existing data may be used, if available, in lieu of sampling done solely for the purpose of this application. All existing data for pollutants specified in paragraphs (g)(7)(i) through (viii) of this section that is collected within four and one-half years of the application must be included in the pollutant data summary submitted by the applicant. If, however, the applicant samples for a specific pollutant on a monthly or more frequent basis, it is only necessary, for such pollutant, to summarize all data collected within one year of the application.

* * * * *

(h) * * *

(1) *Outfall location*. Outfall number, latitude and longitude to the nearest second, including the method of collection, and the name of the receiving water.

* * * * *

(i) * * *

(1) * * *

(iii) Latitude and longitude of the production area (entrance to production area) to the nearest second, including method of collection;

* * * * *

(j) * * *

(1) * * *

(i) *Facility information*. Name, mailing address, and location of the facility, including the latitude and longitude to the nearest second and method of collection, for which the application is submitted;

(ii) *Applicant information*. Name, mailing address, telephone number, and electronic mail address of the applicant, and indication as to whether the applicant is the facility's owner, operator, or both;

* * * * *

(viii) * * *

(D) * * *

(*2*) The name, mailing address, contact person, phone number, and electronic mail address of the organization transporting the discharge, if the transport is provided by a party other than the applicant;

(*3*) The name, mailing address, contact person, phone number, electronic mail address and NPDES permit number (if any) of the receiving facility; and

* * * * *

(ix) An indication of whether applicant is operating under or requesting to operate under a variance as specified at 40 CFR 122.21(n).

* * * * *

(3) * * *

(i) * * *

(C) Latitude and longitude, to the nearest second, including the method of collection;

(4) * * *. (i) As provided in paragraphs (j)(4)(ii) through (x) of this section, all applicants must submit to the Director effluent monitoring information for samples taken from each outfall through which effluent is discharged to waters of the United States, except for CSOs. The Director may allow applicants to submit sampling data for only one outfall on a case-by-case basis, where the applicant has two or more outfalls with substantially identical effluent. The Director may also allow applicants to composite samples from one or more outfalls that discharge into the same mixing zone. For POTWs applying prior to commencement of discharge, data shall be submitted no later than 18 months after the commencement of discharge;

* * * * *

(5) * * *. (i) All applicants must provide an identification of any whole effluent toxicity tests conducted during the four and one-half years prior to the date of the application on any of the applicant's discharges or on any receiving water near the discharge. For POTWs applying prior to commencement of discharge, data shall be submitted no later than 18 months after the commencement of discharge.

* * * * *

(6) * * *

(i) Number of significant industrial users (SIUs) and non-significant categorical industrial users (NSCIUs), as defined at 40 CFR 403.3(v), including trucked or hauled waste, discharging to the POTW; and

(ii) POTWs with one or more SIUs or NSCIUs shall provide the following information for each SIU and NSCIU that discharges to the POTW:

* * * * *

(B) Description of all industrial processes that affect or contribute to the SIU's or NSCIU's discharge;

(C) Principal products and raw materials of the SIU that affect or contribute to the SIU's or NSCIU's discharge;

* * * * *

(E) Whether the SIU or NSCIU is subject to local limits;

* * * * *

(G) Whether any problems at the POTW (*e.g.,* upsets, pass through, interference) have been attributed to the SIU or NSCIU in the past four and one-half years.

* * * * *

(8) * * *
(ii) * * *
(A) * * *

(*3*) Latitude and longitude, to the nearest second, including the method of collection; and

* * * * *

(9) *Contractors.* All applicants must provide the name, mailing address, telephone number, electronic mail address and responsibilities of all contractors responsible for any operational or maintenance aspects of the facility; and

* * * * *

(k) *Application requirements for new sources and new discharges.* New manufacturing, commercial, mining and silvicultural dischargers applying for NPDES permits (except for new discharges of facilities subject to the requirements of paragraph (h) of this section or new discharges of storm water associated with industrial activity which are subject to the requirements of § 122.26(c)(1) and this section (except as provided by § 122.26(c)(1)(ii)) shall provide the following information to the Director, using the application forms provided by the Director:

(1) *Expected outfall location.* The latitude and longitude to the nearest second, including the method of collection, and the name of the receiving water.

* * * * *

(5) * * *

(vi) No later than 18 months after the commencement of discharge from the proposed facility, the applicant is required to complete and submit items V and VI of NPDES application Form 2C (see § 122.21(g)). However, the applicant need not complete those portions of Item V requiring tests which have already been performed and reported under the discharge monitoring requirements of the NPDES permit.

* * * * *

(q) * * *
(1) * * *

(i) The name, mailing address, and location, including latitude and longitude to the nearest second and method of collection, of the TWTDS for which the application is submitted;

* * * * *

(2) * * *

(i) The name, mailing address, telephone number, and electronic mail address,

* * * * *

(8) * * *
(ii) * * *

(A) The name, mailing address, and location, including the latitude and longitude to the nearest second and the method of collection, of the other facility;

* * * * *

(vi) If sewage sludge from the applicant's facility is provided to another "person who prepares," as defined at 40 CFR 503.9(r), and the sewage sludge is not subject to paragraph (q)(8)(iv) of this section, the applicant must provide the following information for each facility receiving the sewage sludge:

(A) The name, mailing address, and electronic mail address of the receiving facility;

* * * * *

(9) * * *
(iii) * * *

(B) The site's latitude and longitude to the nearest second and method of collection;

* * * * *

(D) The name, mailing address, telephone number, and electronic mail address of the site owner, if different from the applicant;

(E) The name, mailing address, telephone number, and electronic mail address of the person who applies sewage sludge to the site, if different from the applicant;

* * * * *

(iv) * * *

(A) Whether the applicant has contacted the permitting authority in the State where the bulk sewage sludge subject to § 503.13(b)(2) will be applied, to ascertain whether bulk sewage sludge subject to § 503.13(b)(2) has been applied to the site on or since July 20, 1993, and if so, the name of the permitting authority and the name, phone number, and electronic mail address if available, of a contact person at the permitting authority;

* * * * *

(10) * * *
(ii) * * *

(A) The site name or number, contact person, mailing address, telephone number, and electronic mail address for the surface disposal site; and

* * * * *

(iii) * * *

(B) The unit's latitude and longitude to the nearest second and method of collection;

* * * * *

(K) * * *

(*1*) The name, contact person, mailing address, and electronic mail address of the facility; and

* * * * *

(11) * * *
(ii) * * *

(A) The name and/or number, contact person, mailing address, telephone number, and electronic mail address of the sewage sludge incinerator; and

* * * * *

(iii) * * *

(B) The incinerator's latitude and longitude to the nearest second and method of collection;

* * * * *

(12) * * *

(i) The name, contact person, mailing address, electronic mail address, location (including latitude and longitude to the nearest second and the method of collection), and all applicable permit numbers of the MSWLF;

* * * * *

(13) *Contractors.* All applicants must provide the name, mailing address, telephone number, electronic mail address and responsibilities of all contractors responsible for any operational or maintenance aspects of the facility related to sewage sludge generation, treatment, use, or disposal;

* * * * *

(r) * * *
(3) * * *

(ii) Latitude and longitude to the nearest second and the method of collection for each cooling water intake structure;

* * * * *

Subpart C—Permit Conditions

■ 4. Section 122.44 is amended by:
■ a. Revising paragraphs (d)(1) introductory text and (d)(1)(ii);
■ b. Adding paragraph (d)(1)(vii)(C);
■ c. Revising the note to paragraph (k)(4);
■ d. Revising paragraph (l)(2); and,
■ e. Adding paragraph (l)(3).

The additions and revisions read as follows:

§ 122.44 Establishing limitations, standards, and other permit conditions (applicable to State NPDES programs, see § 123.25).

* * * * *

(d) * * *

(1) Achieve water quality standards established under section 303 of the CWA, including State narrative criteria for water quality, and ensure consistency with the State antidegradation policy established under § 131.12.

* * * * *

(ii) When determining whether a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above a narrative or numeric criteria within a State water quality standard, the permitting authority shall use procedures which account for existing controls on point and nonpoint sources of pollution, the variability of the pollutant or pollutant parameter in the effluent, the sensitivity of the species to toxicity testing (when evaluating whole effluent toxicity), the use of relevant qualitative or quantitative data, analyses, or other information on pollutants or pollutant parameters to assess the need for a water quality-based effluent limitation, and where appropriate, the dilution of the effluent in the receiving water. A dilution allowance under this paragraph must comply with applicable dilution and mixing zone requirements and low flows established in State water quality standards and must be supported by data or analyses that account for the presence of each assessed pollutant or pollutant parameter in the receiving water (see fact sheet requirements at § 124.56(a)).

* * * * *

(vii) * * *

(C) Any dilution allowance complies with applicable dilution and mixing zone requirements and low flows established in State water quality standards and must be supported by data or analyses quantifying or accounting for the presence of each limited pollutant or pollutant parameter in the receiving water (see fact sheet requirements at § 124.56(a)).

* * * * *

(k) * * *

(4) * * *

Note to Paragraph (k)(4): Additional technical information on BMPs and the elements of BMPs is contained in the following documents: Guidance Manual for Developing Best Management Practices (BMPs), October 1993, EPA No. 833/B–93–004, NTIS No. PB 94–178324, ERIC No. W498); Storm Water Management for Construction Activities: Developing Pollution Prevention Plans and Best Management Practices, September 1992, EPA No. 832/R–92–005, NTIS No. PB 92–235951, ERIC No. N482); Storm Water Management for Construction Activities, Developing Pollution Prevention Plans and Best Management Practices: Summary Guidance, EPA No. 833/R–92–001, NTIS No. PB 93–223550; ERIC No. W139; Storm Water Management for Industrial Activities, Developing Pollution Prevention Plans and Best Management Practices, September 1992; EPA 832/R–92–006, NTIS No. PB 92–235969, ERIC No. N477; Storm Water Management for Industrial Activities, Developing Pollution Prevention Plans and Best Management Practices: Summary Guidance, EPA 833/R–92–002, NTIS No. PB 94–133782; ERIC No. W492. EPA guidance documents can be obtained through the National Service Center for Environmental Publications (NSCEP) at *http://www.epa.gov/nscep*. In addition, States may have BMP guidance documents.

* * * * *

(l) * * *

(2)(i) In the case of effluent limitations established on the basis of section 402(a)(1)(B) of the CWA, a permit may not be renewed, reissued, or modified on the basis of effluent guidelines promulgated under section 304(b) subsequent to the original issuance of such permit, to contain effluent limitations which are less stringent than the comparable effluent limitations in the previous permit.

(ii) In the case of effluent limitations established on the basis of section 301(b)(1)(C) or section 303(d) or (e) of the CWA, a permit may not be renewed, reissued, or modified to contain effluent limitations that are less stringent than the comparable effluent limitations in the previous permit except in compliance with paragraph (l)(3) of this section.

(iii) *Exceptions.* A permit with respect to which paragraph (l)(2) of this section applies may be renewed, reissued, or modified to contain a less stringent effluent limitation applicable to a pollutant, if:

(A) Material and substantial alterations or additions to the permitted facility occurred after permit issuance which justify the application of a less stringent effluent limitation;

(B)(*1*) Information is available which was not available at the time of permit issuance (other than revised regulations, guidance, or test methods) and which would have justified the application of a less stringent effluent limitation at the time of permit issuance; or

(*2*) The Administrator determines that technical mistakes or mistaken interpretations of law were made in issuing the permit under section 402(a)(1)(b);

(C) A less stringent effluent limitation is necessary because of events over which the permittee has no control and for which there is no reasonably available remedy;

(D) The permittee has received a permit modification under section 301(c), 301(g), 301(h), 301(i), 301(k), 301(n), or 316(a); or

(E) The permittee has installed the treatment facilities required to meet the effluent limitations in the previous permit and has properly operated and maintained the facilities but has nevertheless been unable to achieve the previous effluent limitations, in which case the limitations in the reviewed, reissued, or modified permit may reflect the level of pollutant control actually achieved (but shall not be less stringent than required by effluent guidelines in effect at the time of permit renewal, reissuance, or modification).

(iv) *Limitations.* In no event may a permit with respect to which paragraph (l)(2) of this section applies be renewed, reissued, or modified to contain an effluent limitation which is less stringent than required by effluent guidelines in effect at the time the permit is renewed, reissued, or modified. In no event may such a permit to discharge into waters be renewed, issued, or modified to contain a less stringent effluent limitation if the implementation of such limitation would result in a violation of a water quality standard under section 303 applicable to such waters.

Note to paragraph (l)(2). Paragraph (2)(iii)(B)(*1*) of this section shall not apply to any revised waste load allocations or any alternative grounds for translating water quality standards into effluent limitations, except where the cumulative effect of such revised allocations results in a decrease in the amount of pollutants discharged into the concerned waters, and such revised allocations are not the result of a discharger eliminating or substantially reducing its discharge of pollutants due to complying with the requirements of this chapter or for reasons otherwise unrelated to water quality.

(3)(i) *Standard Not Attained.* For waters identified under section 303(1)(A) of the Act where the applicable water quality standard has not yet been attained, any effluent limitation based on a total maximum daily load or other waste load allocation established under this section may be revised only if: (A) The cumulative effect of all such revised effluent limitations based on such total maximum daily load or waste load allocation will assure the attainment of such water quality standard, or (B) the designated use which is not being attained is removed in accordance with regulations established under this section.

(ii) *Standard Attained.* Any effluent limitation based on a total maximum daily load or other waste load allocation established under this section, or any water quality standard established under this section, or any other permitting standard may be revised only if such revision is subject to and consistent with the antidegradation requirements established under this section.

■ 5. Section 122.45 is amended by revising the section heading and paragraph (b)(1) to read as follows:

§ 122.45 Calculating NPDES permit conditions (applicable to State NPDES programs, see 40 CFR 123.25).

* * * * *

(b) *Production-based limitations.* (1) In the case of POTWs, permit effluent limitations, standards, or prohibitions derived from technology-based requirements pursuant to § 125.3(a)(1) shall be calculated based on design flow.

* * * * *

PART 123—STATE PROGRAM REQUIREMENTS

■ 6. The authority citation for part 123 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1252 *et seq.*

Subpart C—Transfer of Information and Permit Review

■ 7. Section 123.44 is amended by adding paragraph (k) to read as follows:

§ 123.44 EPA review of and objections to State permits.

* * * * *

Option 1 for Paragraph (k)(1)

(k)(1) Where a State does not submit a proposed permit (or draft permit, if applicable under paragraph (j) of this section) to EPA within two years, after the expiration of the existing permit, and the permit is administratively continued under state law in accordance with § 122.6(d), EPA may, in its discretion, review the administratively continued permit as a proposed permit, in accordance with the procedures in paragraphs (a)(1) through (h)(3) of this section.

Option 2 for Paragraph (k)(1)

(k)(1) Where a State does not submit a proposed permit (or draft permit, if applicable under paragraph (j) of this section) to EPA within five years, after the expiration of the existing permit, and the permit is administratively continued under state law in accordance with § 122.6(d), EPA may, in its discretion, review the administratively continued permit as a proposed permit, in accordance with the procedures in paragraphs (a)(1) through (h)(3) of this section.

Option 1 for Paragraph (k)(2)

(2) To review an expired and administratively continued permit under this paragraph, EPA must provide the State and the permittee with written notice stating that if a proposed permit (or draft permit, if applicable under paragraph (j) of this section) is not provided within 180 days, the Regional Administrator will designate the expired permit as a proposed permit submitted to EPA for review under this section. EPA may submit this notice any time beginning two years after permit expiration.

Option 2 for Paragraph (k)(2)

(2) To review an expired and administratively continued permit under this paragraph, EPA must provide the State and the permittee with written notice stating that if a proposed permit (or draft permit, if applicable under paragraph (j) of this section) is not provided within 180 days, the Regional Administrator will designate the expired permit as a proposed permit submitted to EPA for review under this section. EPA may submit this notice any time beginning five years after permit expiration.

(3) If the State submits a draft or proposed permit for EPA review at any time before exclusive authority to issue the permit passes to EPA under paragraph (h) of this section, EPA will suspend its designation of the administratively continued permit as a proposed permit under this paragraph and will evaluate the proposed permit (or draft permit, if applicable under paragraph (j) of this section) submitted by the State in accordance with the procedures described in paragraphs (a)(1) through (h)(3) of this section.

(i) If the State does not reissue the permit within 180 days following completion of EPA's review of the draft or proposed permit submitted by the State in accordance with paragraph (k)(3) of this section, EPA may reinstate its designation of the administratively continued permit as the proposed permit, and the procedures and timelines established in paragraphs (a)(1) through (h)(3) of this section will proceed from the point of the suspension. EPA must provide the State and permittee written notice of this decision to reinstate the designation.

(ii) [Reserved]

PART 124—PROCEDURES FOR DECISIONMAKING

■ 8. The authority citation for part 124 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1253 *et seq.*

Subpart A—General Program Requirements

■ 9. Section 124.10 is amended by revising (c) introductory text and adding paragraph (c)(2)(iv) to read as follows:

§ 124.10 Public notice of permit actions and public comment period.

* * * * *

(c) Methods (applicable to State programs, see 40 CFR 123.25 (NPDES), 145.11 (UIC), 233.26 (404), and 271.14 (RCRA)). Public notice of activities described in paragraph (a)(1) of this section shall be given by the following methods:

* * * * *

(2) * * *

(iv) For NPDES major permits and NPDES general permits, in lieu of the requirement to post a notice in a daily or weekly newspaper, as described in paragraph (2)(i) of this section, the Director may post all notices required by this paragraph to the permitting authority's public Web site. If the Director selects this option, in addition to meeting the requirements in § 124.10(d), the Director must post the draft permit and fact sheet on the Web site during the public comment period, and must post the final permit, fact sheet and response to comments (if any) on the Web site from the date of issuance of the permit until the permit is reissued or terminated.

Note to paragraph (c)(2)(iv): The Director is encouraged to ensure that the method(s) of public notice effectively informs all interested communities and allows access to the permitting process for those seeking to participate.

Subpart D—Specific Procedures Applicable to NPDES Permits

■ 10. Section 124.55 is amended by revising paragraph (b) to read as follows:

§ 124.55 Effect of State certification.

* * * * *

(b) If there is a change in the State law or regulation upon which a certification is based, or if a court of competent jurisdiction or appropriate State board or agency stays, vacates, or remands a certification, a State which has issued a certification under § 124.53 may issue a modified certification or notice of waiver and forward it to EPA. If the modified certification or notice of waiver is received before final agency action on the permit, the permit shall be consistent with the more stringent conditions which are based upon State law identified in such certification. If the modified certification or notice of waiver is received after final agency action on the permit, the Regional Administrator may modify the permit to be consistent with any more stringent conditions added to the certification following resolution of an administrative or judicial challenge to the certification. In all other instances where the certification or notice of waiver is received after final agency action on the permit, the Regional Administrator may modify the permit on request of the permittee only to the extent necessary to delete any conditions based on a condition in a certification invalidated by a court of competent jurisdiction or by an appropriate State board or agency.

* * * * *

■ 11. Section 124.56 is amended by:
■ a. Revising paragraphs (a), (b)(1)(vi), and (c); and
■ b. Adding paragraph (b)(1)(vii).

The additions and revision read as follows:

§ 124.56 Fact sheets.

* * * * *

(a) Any calculations or other necessary explanation of the derivation of all effluent limitations, standards and other permit conditions specific to the permitted discharge, including sewage sludge use or disposal conditions. Where effluent limitations and conditions are carried forward from a previous permit, explanation of the basis of the existing limitations and conditions must be included in the fact sheet or administrative record for the draft permit. Where the information in paragraphs (a)(1) and (2) of this section is contained in other documents that are part of the administrative record, the fact sheet may provide a brief summary of the required information and a specific reference to the source document within the administrative record, rather than repeating the information. Where applicable, fact sheets must contain:

(1) For NPDES individual permits:

(i) A citation to the specific federal or state effluent limitation guideline, performance standard, or standard for sewage sludge use or disposal as required by § 122.44 from which effluent limitations and conditions are derived;

(ii) An identification of:

(A) The receiving water(s);

(B) The State water quality standards that apply to the receiving water(s);

(C) The CWA section 303(d)/305(b) assessment status of the receiving water(s), and;

(D) Whether a total maximum daily load has been established for any pollutant or pollutant parameter for which the receiving water(s) is listed as impaired;

(iii) An explanation and calculations for effluent limits or conditions necessary to achieve technology-based standards required by § 122.44(a) and best management practices required pursuant to § 122.44(k);

(iv) An explanation of the basis for the inclusion of requirements in addition to, or more stringent than, promulgated effluent limitations guidelines or standards consistent with § 122.44(d), including, but not limited to, a description of:

(A) How pollutants and pollutant parameters were selected for analysis for the need for effluent limitations under § 122.44(d) to achieve water quality standards, including a summary of effluent characteristics;

(B) The receiving water ambient pollutant concentration data for all pollutants for which a dilution or mixing allowance is granted pursuant to § 122.44(d)(1)(ii), or an explanation of why such data are not applicable or available;

(C) For any proposed water quality-based effluent limitation or condition required by § 122.44(d), any dilution or mixing allowance, including a discussion of how ambient pollutant concentrations were considered in the water quality analysis;

(D) If an EPA-approved or established total maximum daily load has assigned a waste load allocation to the proposed discharge, how permit effluent limitations and conditions were developed consistent with the assumptions of the waste load allocation, and; where the permitting authority determines that a discharge will cause, have a reasonable potential to cause, or contribute to an excursion above any State narrative water quality criterion, how the permit ensures compliance with applicable State narrative water quality criteria consistent with § 122.44(d)(1)(v) and (vi);

(v) For any proposed effluent limitation or condition required by § 122.44, information sufficient to ensure that the discharge is consistent with the State's antidegradation requirements; and

(vi) a discussion of the permit's monitoring and reporting requirements, including an assurance that the prescribed analytical methods meet the requirements of § 122.44(i).

(2) For NPDES general permits:

(i) A description of how the issuance of the general permit conforms with the requirements of § 122.28, including the geographic area of coverage, the types, classes, or categories of waters to which the general permit authorizes discharge, and the sources that will be covered by the general permit;

(ii) A citation to the specific federal or State effluent limitation guideline, performance standard, or standard for sewage sludge use or disposal as required by § 122.44 from which effluent limitations and conditions are derived;

(iii) A description and rationale for other requirements included in the general permit, including effluent limits or conditions necessary to achieve technology-based standards required by § 122.44(a) and best management practices required pursuant to § 122.44(k);

(iv) A description of how the general permit ensures that discharges are controlled as necessary to meet applicable State water quality standards, including consideration of State antidegradation policies and applicable waste load allocations from EPA approved or established total maximum daily loads, in accordance with the requirements of § 122.44(d);

(v) A discussion of proposed monitoring and reporting conditions, including assurance that prescribed analytical methods meet the requirements of § 122.44(i); and

(vi) A description of the Notice of Intent information and submission requirements, and the process by which the permit provides authorization to discharge or authorization to engage in sludge use and disposal practices. Where the general permit does not require a Notice of Intent, a description of why the Notice of Intent process is inappropriate in accordance with the criteria established in § 122.28(b)(2)(v).

(b)(1) * * *

(vi) Waivers from monitoring requirements granted under § 122.44(a) of this chapter; or

(vii) Compliance schedules granted under § 122.47 of this chapter.

* * * * *

(c) When appropriate, a sketch or detailed description of the location of each discharge or regulated activity, including the geographic coordinates, described in the application; and

* * * * *

PART 125—CRITERIA AND STANDARDS FOR THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

■ 12. Revise the authority citation for part 125 to read as follows:

Authority: The Clean Water Act, 33 U.S.C., 1251 *et seq.*

Subpart A—Criteria and Standards for Imposing Technology-Based Treatment Requirements Under Sections 301(b) and 402 of the Act

§ 125.3 [Amended]

■ 13. Section 125.3 is amended by removing and reserving paragraph (a)(1)(ii).

[FR Doc. 2016–11265 Filed 5–17–16; 8:45 am]

BILLING CODE 6560–50–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Wednesday,
No. 96 May 18, 2016

Part IV

Department of Health and Human Services

Office of the Secretary

45 CFR Part 92
Nondiscrimination in Health Programs and Activities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 92

RIN 0945–AA02

Nondiscrimination in Health Programs and Activities

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: This final rule implements Section 1557 of the Affordable Care Act (ACA) (Section 1557). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. The final rule clarifies and codifies existing nondiscrimination requirements and sets forth new standards to implement Section 1557, particularly with respect to the prohibition of discrimination on the basis of sex in health programs other than those provided by educational institutions and the prohibition of various forms of discrimination in health programs administered by the Department of Health and Human Services (HHS or the Department) and entities established under Title I of the ACA. In addition, the Secretary is authorized to prescribe the Department's governance, conduct, and performance of its business, including, here, how HHS will apply the standards of Section 1557 to HHS-administered health programs and activities.

DATES: *Effective Date:* This rule is effective July 18, 2016.

Applicability Dates: The provisions of this rule are generally applicable on the date the rule is effective, except to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Eileen Hanrahan at (800) 368–1019 or (800) 537–7697 (TDD).

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys),* a service of the U.S. Government Printing Office. This database can be accessed via the Internet at *http://www.gpo.gov/fdsys.*

I. Background

Section 1557 of the ACA provides that an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d *et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. 1681 *et seq.* (sex), the Age Discrimination Act of 1975 (Age Act), 42 U.S.C. 6101 *et seq.* (age), or Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794 (disability), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the Act or its amendments. Section 1557 states that the enforcement mechanisms provided for and available under Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of addressing violations of Section 1557.

Section 1557(c) of the ACA authorizes the Secretary of the Department to promulgate regulations to implement the nondiscrimination requirements of Section 1557. In addition, the Secretary is authorized to prescribe regulations for the Department's governance, conduct, and performance of its business, including how HHS applies the standards of Section 1557 to HHS-administered health programs and activities.[1]

A. Regulatory History

On August 1, 2013, the Office for Civil Rights of the Department (OCR) published a Request for Information (RFI) in the **Federal Register** to solicit information on issues arising under Section 1557. OCR received 402 comments; one-quarter (99) were from organizational commenters, with the remainder from individuals.

On September 8, 2015, OCR issued a proposed rule, "Nondiscrimination in Health Programs and Activities," in the **Federal Register**, and invited comment on the proposed rule by all interested parties.[2] The comment period ended on November 9, 2015. In total, we received approximately 24,875 comments on the proposed rule. Comments came from a wide variety of stakeholders, including, but not limited to: Civil rights/advocacy groups, including language access organizations, disability rights organizations, women's organizations, and organizations serving lesbian, gay, bisexual, or transgender (LGBT) individuals; health care providers; consumer groups; religious organizations; academic and research institutions; reproductive health organizations; health plan organizations; health insurance issuers; State and local agencies; and tribal organizations. Of the total comments, 23,344 comments were from individuals. The great majority of those comments were letters from individuals that were part of mass mail campaigns organized by civil rights/advocacy groups.

B. Overview of the Final Rule

This final rule adopts the same structure and framework as the proposed rule: Subpart A sets forth the rule's general provisions; Subpart B contains the rule's nondiscrimination provisions; Subpart C describes specific applications of the prohibition on discrimination to health programs and activities; and Subpart D describes the procedures that apply to enforcement of the rule.

OCR has made some changes to the proposed rule's provisions, based on the comments we received. Among the significant changes are the following.

Section 92.4 now provides a definition of the term "national origin."

OCR decided against including a blanket religious exemption in the final rule; however, the final rule includes a provision noting that insofar as application of any requirement under the rule would violate applicable Federal statutory protections for religious freedom and conscience, such application would not be required.

OCR has modified the notice requirement in § 92.8 to exclude publications and significant communications that are small in size from the requirement to post all of the content specified in § 92.8; instead, covered entities will be required to post only a shorter nondiscrimination statement in such communications and publications, along with a limited number of taglines. OCR also is translating a sample nondiscrimination statement that covered entities may use in fulfilling this obligation. It will be available by the effective date of this rule.

In addition, with respect to the obligation in § 92.8 to post taglines in at least the top 15 languages spoken nationally by persons with limited English proficiency, OCR has replaced the national threshold with a threshold requiring taglines in at least the top 15 languages spoken by limited English proficient populations statewide.

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[1] 5 U.S.C. 301.

[2] 80 FR 54172 (Sept. 8, 2015).

OCR has changed § 92.101 to provide that sex-specific health programs or activities are allowable only where the covered entity can demonstrate an exceedingly persuasive justification, *i.e.,* that the sex-specific program is substantially related to the achievement of an important health-related or scientific objective.

OCR has changed § 92.201, addressing the obligation to take reasonable steps to provide meaningful access. That section now requires the Director to evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue to the individual with limited English proficiency, and to take into account all other relevant factors, including whether the entity has developed and implemented an effective language access plan, appropriate to its particular circumstances. The final rule deletes the specific list of illustrative factors set out in the proposed rule.

Also, OCR has changed § 92.203, addressing accessibility of buildings and facilities for individuals with disabilities, to require covered entities that were covered by the 2010 Americans with Disabilities Act (ADA) Standards for Accessible Design prior to the effective date of this final rule to comply with those standards for new construction or alterations by the effective date of the final rule. The final rule also narrows § 92.203's safe harbor for building and facility accessibility so that compliance with the Uniform Federal Accessibility Standards (UFAS) will be deemed compliance with this part only if construction or alteration was commenced before the effective date of the final rule and the facility or part of the facility was not covered by standards under the ADA. As nearly all covered entities under the final rule are already covered by the ADA standards, these changes impose a de minimis cost.

Section 92.301 has been changed to clarify that compensatory damages for violations of Section 1557 are available in administrative and judicial actions to the extent they are available under the authorities referenced in Section 1557. Finally, we have added a severability clause to § 92.2, to indicate our intention that the rule be construed to give the maximum effect permitted by law to each provision.

In responding to the comments it received on the proposed rule, OCR has provided a thorough explanation of each of these changes in the preamble. OCR has also clarified some of the nondiscrimination requirements of Section 1557 and made some technical changes to the rule's provisions. In addition, we have added some definitions to proposed § 92.4, as summarized in the preamble to this final rule.

II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments

A. General Comments

OCR received a large number of comments asking that we categorically declare in the final rule that certain actions are or are not discriminatory. For example, some commenters asked that OCR state that a modification to add medically necessary care, or a prohibition on exclusions of medically necessary services, is never a fundamental alteration to a health plan. Similarly, other commenters asked that OCR include a statement in the final rule that an issuer's refusal to cover core services commonly needed by individuals with intellectual disabilities is discrimination on the basis of disability. Still other commenters asked that OCR state that limiting health care and gender transition services to transgender individuals over the age of 18 is discriminatory. Other commenters asked that OCR state that it is discriminatory to require individuals with psychiatric disabilities to see a mental health professional in order to continue receiving treatment for other conditions.

Many of these same commenters asked that OCR supplement the final rule with in-depth explanations and analyses of examples of discrimination. For example, several commenters asked that OCR add an example of discrimination in research trials. Similarly, many other commenters asked that OCR add an example of what they considered to be disability discrimination in health insurance practices, such as higher reimbursement rates for care in segregated settings.

OCR appreciates the commenters' desire for further information on the application of the rule to specific circumstances. OCR's intent in promulgating this rule is to provide consumers and covered entities with a set of standards that will help them understand and comply with the requirements of Section 1557. Covered entities should bear in mind the purposes of the ACA and Section 1557—to expand access to care and coverage and eliminate barriers to access—in interpreting requirements of the final rule. But we neither address every scenario that might arise in the application of these standards nor state that certain practices as a matter of law are "always" or "never" permissible. The determination of whether a certain practice is discriminatory typically requires a nuanced analysis that is fact-dependent. Nonetheless, OCR has included in the preamble a number of examples of issues and circumstances that may raise compliance concerns under the final rule.

OCR also received several comments, primarily from representatives of the insurance industry, recommending that where specific Centers for Medicare & Medicaid Services (CMS) or State requirements apply to covered entities, OCR should either (1) harmonize all standards with existing CMS rules, or (2) allow issuers to be deemed compliant with Section 1557 if they are compliant with existing Federal or State law. For example, some commenters requested that compliance with CMS regulations that pertain to qualified health plans or insurance benefit design, such as prescription drug formularies designed by a pharmacy and therapeutics committee, be deemed compliance with the final rule on Section 1557. These commenters were concerned that CMS or a State might approve a plan that OCR might later find discriminatory. The commenters sought clarification on how OCR will handle cases involving health plans regulated by multiple authorities, and suggested that a "deeming" approach would reduce confusion and avoid duplication of costs and administrative effort. Other commenters asked that compliance with language access standards promulgated by CMS or the States be deemed compliance with the final rule; those comments are discussed in more detail in the preamble at § 92.201.

OCR recognizes the efficiencies inherent in harmonizing regulations to which covered entities are subject under various laws. Indeed, entities covered under Section 1557 are likely also subject to a host of other laws and regulations, including CMS regulations, the Genetic Information Nondiscrimination Act of 2008,[3] the Family and Medical Leave Act, the ADA, Title VII of the Civil Rights Act of 1964, and State laws. OCR will coordinate as appropriate with other Federal agencies to avoid inconsistency and duplication in enforcement efforts.

That said, OCR declines to adopt a deeming approach whereby compliance with another set of laws or regulations automatically constitutes compliance with Section 1557. As to State laws, it is inappropriate to define requirements under Federal law based on what could be the varying, and potentially changing, requirements of different States' approaches. As to other Federal laws, OCR will give consideration to an entity's compliance with the requirements of other Federal laws where those requirements overlap with Section 1557. In such cases, OCR will work closely with covered entities where compliance with this final rule requires additional steps. But in the final analysis, OCR must, in its capacity as the lead enforcement agency for Section 1557, maintain the discretion to evaluate an entity's compliance with the standards set by the final rule. This is consistent with the approach taken by other agencies to civil rights obligations, in which compliance with one set of requirements, adopted under different laws or for different purposes, is not considered automatic compliance with civil rights obligations.

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[3] Public Law 110–233, 122 Stat. 881 (2008).

Subpart A—General Provisions

Purpose and Effective Date (§ 92.1)

In § 92.1, we proposed that the purpose of this part is to implement Section 1557 of the ACA, which prohibits discrimination in certain health programs and activities on the grounds prohibited under Title VI, Title IX, the Age Act, and Section 504, which together prohibit discrimination on the basis of race, color, national origin, sex, age, or disability.

We also proposed that the effective date of the Section 1557 implementing regulation shall be 60 days after the publication of the final rule in the **Federal Register**.

The comments and our responses regarding the proposed effective date are set forth below.

Comment: Some commenters asserted that 60 days after publication of the final rule did not allow sufficient time for entities to come into compliance with Section 1557 and requested that the effective date be one year after publication of the final rule. Similarly, one commenter stated that State agencies covered by Section 1557 need at least 150 days to come into compliance with Section 1557. The commenter stated that State agencies need additional time to assess the impacts, align nondiscrimination requirements from multiple Federal agencies, and make the required policy, operational, and system changes.

Response: OCR does not believe that extending the effective date beyond 60 days is warranted, except with regard to specific provisions for which there is a later applicability date, as set forth below. Most of the requirements of Section 1557 are not new to covered entities, and 60 days should be sufficient to come into compliance with any new requirements.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.1 with one modification. We recognize that some covered entities will have to make changes to their health insurance coverage or other health coverage to bring that coverage into compliance with this final rule. We are sensitive to the difficulties that making changes in the middle of a plan year could pose for some covered entities and are committed to working with covered entities to ensure that they can comply with the final rule without causing excessive disruption for the current plan year. Consequently, to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

Application (§ 92.2)

Section 92.2 of the proposed rule stated that Section 1557 applies to all health programs and activities, any part of which receives Federal financial assistance from any Federal agency. It also stated that Section 1557 applies to all programs and activities that are administered by an Executive Agency or any entity established under Title I of the ACA.

In paragraph (a), we proposed to apply the proposed rule, except as otherwise provided in § 92.2, to: (1) All health programs and activities, any part of which receives Federal financial assistance administered by HHS; (2) health programs and activities administered by the Department, including the Federally-facilitated Marketplaces; and (3) health programs and activities administered by entities established under Title I of the ACA, including the State-based Marketplaces.

In paragraph (b), we proposed limitations to the application of the final rule. We proposed the adoption of the existing limitations and exceptions that already, under the statutes referenced in Section 1557, govern the health programs and activities subject to Section 1557. We noted that these limitations and exceptions are found in the Age Act and in the regulations implementing the Age Act, Section 504, and Title VI, which apply to all programs and activities that receive Federal financial assistance.

In paragraph (b)(1), we proposed to incorporate the exclusions found in the Age Act, such that the provisions of the proposed rule would not apply to any age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which provides any benefits or assistance to persons based on age, establishes criteria for participation in age-related terms, or describes intended beneficiaries to target groups in age-related terms.[4] We requested comment on whether the exemptions found in Title IX and its implementing regulation should be incorporated into the final rule. We noted that unlike the Age Act, Section 504, and Title VI, which apply to all programs and activities that receive Federal financial assistance (including health programs and activities), Title IX applies only in the context of education programs and not to the majority of the health programs and activities subject to the proposed rule. In addition, we noted that many of Title IX's limitations and exceptions do not readily apply in a context that is grounded in health care, rather than education.

We invited comment on whether the regulation should include any specific exemptions for health service providers, health plans, or other covered entities with respect to requirements of the proposed rule related to sex discrimination. We stated that we wanted to ensure that the proposed rule had the proper scope and appropriately protected sincerely held religious beliefs to the extent that those beliefs may conflict with provisions of the proposed regulation. We noted that certain protections already exist with respect to religious beliefs, particularly with respect to the provision of certain health-related services; for example, we noted that the proposed rule would not displace the protections afforded by provider conscience laws,[5] the Religious Freedom Restoration Act (RFRA),[6] provisions in the ACA related to abortion services,[7] or regulations issued under the ACA related to preventive health services.[8] We invited comment on the extent to which these existing protections provide sufficient safeguards for any religious concerns in applying Section 1557.

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[4] *See* 42 U.S.C. 6103(b).

[5] *See, e.g.,* 42 U.S.C. 300a–7; 42 U.S.C. 238n; Consolidated and Further Continuing Appropriations Act 2015, Public Law 114–53, Div. G, § 507(d) (Dec. 16, 2015).

[6] 42 U.S.C. 2000bb–1.

[7] *See, e.g.,* 42 U.S.C. 18023.

We noted that a fundamental purpose of the ACA is to ensure that health services are available broadly on a nondiscriminatory basis to individuals throughout the country. Thus, we requested comment on any health care consequences that would ensue were the regulation to provide additional exemptions.

We also requested comment on the scope of additional exemptions, if any, that should be included and the processes for claiming them, including whether those processes should track those used under Title IX, at 45 CFR 86.12.

The comments and our responses regarding § 92.2 are set forth below.

Comment: Some commenters recommended that the final rule apply not only to health programs and activities receiving Federal financial assistance from the Department, but to health programs and activities receiving Federal financial assistance from other Departments. The commenters noted that in enacting Section 1557, Congress delegated rulemaking authority to the Department; they therefore maintained that the Department has the authority to promulgate rules that apply to other Departments. Commenters further noted that the Department has greater expertise in the application of civil rights laws to health programs and activities than do other Departments, and further urged that HHS regulations applicable to health programs and activities receiving Federal financial assistance from other Departments would be afforded deference under *Chevron U.S.A.* v. *NRDC, Inc.*[9]

In the alternative, commenters recommended that we collaborate with other Departments to effectuate the provisions of the final rule and ensure that other Departments enter into delegation agreements or Memoranda of Understanding that grant HHS interpretation and enforcement authority over health programs funded and administered by other Departments or that commit other Departments to move quickly to engage in their own rulemaking on Section 1557.

Response: While the rule recognizes that Section 1557 itself applies to health programs and activities receiving Federal financial assistance from other Departments, we decline to extend the scope of the rule to health programs and activities receiving Federal financial assistance from other Departments. Drafting a rule applicable to health programs and activities assisted by other Departments would pose numerous challenges, one of which is that the Department lacks the information and expertise necessary to apply the rule to those programs without further engagement and collaboration with those Departments. We agree that expeditious implementation of Section 1557 by other Departments is desirable, and hope that the Department's final rule will inform enforcement of Section 1557 by other Departments with respect to their federally assisted health programs and activities. To this end, the OCR Director sent a memorandum encouraging coordination of enforcement responsibilities under Section 1557 to all Federal agencies in November 2015.

Comment: Commenters recommended that the final rule apply not just to programs administered by HHS, but also to programs administered by other Departments.

Response: We decline to make the rule applicable to programs administered by other Departments. We will, however, continue to work with other Departments that administer health programs and activities to help those Departments ensure that their programs are nondiscriminatory.

Comment: Many commenters responded to the proposed rule's request for comment on whether the rule should include a religious exemption for health care providers, health plans, or other covered entities with respect to the requirements of the rule related to sex discrimination, or whether existing protections, including RFRA, ACA regulations for preventive health services, and Federal provider conscience laws provide sufficient safeguards for religious concerns.

Most of the organizations that commented on this issue, including professional medical associations and civil rights organizations, and the overwhelming majority of individual commenters, many of whom identified themselves as religious, opposed any religious exemption on the basis that it would potentially allow for discrimination on the bases prohibited by Section 1557 or for the denial of health services to women. Several religious organizations also opposed a religious exemption, asserting that RFRA, the Federal provider conscience statutes, and State RFRA statutes, which many States have enacted, provide sufficiently strong protections for religious providers and institutions. Many commenters said that mergers of religiously-affiliated hospitals with other hospitals have deepened concerns that would be raised by providing a religious exemption, as the mergers may leave individuals in many communities with fewer health care options offering the full range of women's health services. Many commenters also pointed to the language in the majority opinion in the Supreme Court's decision in *Hobby Lobby* v. *Burwell* that RFRA is not a shield that permits discrimination "cloaked as religious practice to escape legal sanction."[10]

Some religious organizations that submitted comments strongly supported a religious exemption, arguing that faith-based health care providers and employers would be substantially burdened if required to provide or refer for, or purchase insurance covering, particular services such as gender transition services. Supporters of an exemption recommended that Section 1557 incorporate the religious exemption in Title IX, which exempts educational institutions controlled by religious organizations from the prohibition of sex discrimination if the application would be inconsistent with the religious tenets of the organization.[11] None of the commenters supporting a religious exemption asserted that there would be a religious basis for generally refusing to treat LGBT individuals for a medical condition, for example, refusing to treat a broken bone or cancer; rather, commenters asserted that the rule should exempt faith-based providers from providing particular services, such as services related to gender transition, that are inconsistent with their religious beliefs.

Response: As noted in the preamble to the proposed rule, certain protections already exist in Federal law with respect to religious beliefs, particularly with regard to the provision of certain health-related services. For example, we noted that the proposed rule would not displace the protections afforded by provider conscience laws,[12] RFRA,[13] provisions in the ACA related to abortion services,[14] or regulations issued under the ACA related to preventive health services.[15] Nothing in this final rule displaces those protections.

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[8] *See* 45 CFR 147.131.

[9] 467 U.S. 837 (1984).

[10] 132 S. Ct. 2751, 2783 (2014).

[11] 20 U.S.C. 1681(a)(3).

[12] *See, e.g.,* 42 U.S.C. 300a–7; 42 U.S.C. 238n; Consolidated and Further Continuing Appropriations Act 2015, Pub. L. 114–53, Div. G, § 507(d) (Dec. 16, 2015).

[13] 42 U.S.C. 2000bb–1.

[14] *See, e.g.,* 42 U.S.C. 18023.

[15] *See* 45 CFR 147.131.

Although some commenters urged us also to incorporate Title IX's blanket religious exemption into this final rule, we believe that applying the protections in the laws identified above offers the best and most appropriate approach for resolving any conflicts between religious beliefs and Section 1557 requirements. With regard to abortion, for example, specific ACA provisions concerning abortion will continue to control, including, but not limited to, provisions that bar qualified health plans offered through a Marketplace℠ [16] from discriminating against an individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions,[17] and provisions that state that nothing in the ACA shall be construed to require a qualified health plan to provide coverage of abortion as an essential health benefit.[18]

In other cases, application of RFRA is the proper means to evaluate any religious concerns about the application of Section 1557 requirements. The RFRA analysis evaluates whether a legal requirement substantially burdens the exercise of religion; if so, the question becomes whether the legal requirement furthers a compelling interest and is the least restrictive means to further that interest.

We believe that the government has a compelling interest in ensuring that individuals have nondiscriminatory access to health care and health coverage and, under RFRA, would assess whether a particular application of Section 1557 substantially burdened a covered entity's exercise of religion and, if so, whether there were less restrictive alternatives available. Claims under RFRA are individualized and fact specific and we would make these determinations on a case-by-case basis, based on a thorough analysis and relying on the extensive case law interpreting RFRA standards.

We decline to adopt commenters' suggestion that we import Title IX's blanket religious exemption [19] into Section 1557. Section 1557 itself contains no religious exemption. In addition, Title IX and its exemption are limited in scope to educational institutions, and there are significant differences between the educational and health care contexts that warrant different approaches.

First, students or parents selecting religious educational institutions typically do so as a matter of choice; a student can attend public school (if K–12) or choose a different college. In the health care context, by contrast, individuals may have limited or no choice of providers, particularly in rural areas or where hospitals have merged with or are run by religious institutions. Moreover, the choice of providers may be even further circumscribed in emergency circumstances.

Second, a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results. Thus, it is appropriate to adopt a more nuanced approach in the health care context, rather than the blanket religious exemption applied for educational institutions under Title IX.

Based on the foregoing, we have included a provision in this final regulation making clear that where application of this regulation would violate applicable Federal statutory protections for religious freedom and conscience, that application will not be required. The Department also retains the discretion to provide other accommodations or exemptions where permitted by Federal law and supported by sound public policy.

Comment: One commenter suggested that we clarify that the regulation applies only to a covered entity's health operations "in the United States."

Response: This regulation applies only to individuals who are subjected to discrimination, at least in part, in the United States and to the provision or administration of health-related services or health-related insurance coverage in the United States, consistent with the four statutes referenced in Section 1557.[20]

Consistent with the Department's Title VI regulation,[21] OCR interprets "United States" to include the U.S. territories. The definition of "recipient" of Federal financial assistance in the civil rights laws referenced in Section 1557 does not contain geographic limitations, and includes, in addition to States and political subdivisions, other "public or private agenc[ies], institution[s], or organization[s]." [22] Thus, health programs and activities of the U.S. Territories, and those provided or administered in the U.S. Territories, are covered by the final rule.[23]

Comment: One commenter requested that we clarify that expatriate health plans, plan sponsors of self-funded expatriate health plans, and issuers of fully-insured expatriate health plans are exempt from Section 1557 pursuant to the Expatriate Health Coverage Clarification Act of 2014 (EHCCA),[24] which provides generally that provisions of the ACA do not apply to expatriate health plans, employer plan sponsors of expatriate health plans, or expatriate health insurance issuers. The commenter noted that the EHCCA does not include any exceptions or special rules pertaining to Section 1557; thus, the commenter asserted, applying Section 1557 to expatriate health plans would be contrary to Congressional intent and would competitively disadvantage American health issuers in the global marketplace, resulting in consumers choosing offshore options and American issuers moving their plans offshore to compete.

Response: Section 3(a) [25] of the EHCCA specifies that the provisions of (including any amendment made by) the ACA and Title I and subtitle B of Title II of the Health Care and Education Reconciliation Act of 2010 shall not apply with respect to expatriate health plans; employers with respect to such plans, solely in their capacity as plan sponsors for such plans; or expatriate health insurance issuers with respect to coverage offered by such issuers under such plans, subject to the exceptions and special rules enumerated in Sections 3(B) and 3(C) of the EHCCA. Section 1557 is contained in Title I of the ACA; thus, pursuant to the EHCCA, Section 1557 does not apply with respect to expatriate health plans, expatriate health insurance issuers, or employer plan sponsors of expatriate plans, as defined in the EHCCA.

Comment: Tribes and tribal organizations submitted comments recommending that we make a number of changes throughout the rule and preamble to address the application of the rule to tribes and tribal health programs. Commenters objected to the characterization of 45 CFR 80.3(d), the exception in the Title VI regulation for

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[16] Health Insurance Marketplace℠ and Marketplace℠ are service marks of the U.S. Department of Health and Human Services.

[17] 42 U.S.C. 18023(b)(4).

[18] 42 U.S.C. 18023(b)(1)(A).

[19] 42 U.S.C. 18116(a).

[20] 20 U.S.C. 1681(a); 29 U.S.C. 794(a); 42 U.S.C. 2000d; 42 U.S.C. 6102.

[21] 45 CFR 80.13(e).

[22] 45 CFR 80.13(i) (Title VI); 84.3(f) (Section 504); 86.2(i) (Title IX); 90.4 (Age Act).

[23] OCR notes that in contrast to Section 1557, which does not refer to the United States or to "states," other ACA provisions refer to "states" and the Department has interpreted the meaning of "state" in the context of those statutory requirements. See 45 CFR 144.103.

[24] Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113–235, Div. M, § 3 (codified at 42 U.S.C. 18014).

[25] 42 U.S.C. 18014(f).

Indian health programs and other programs limited by Federal law to individuals of a particular race, color, or national origin, that has been incorporated into the Section 1557 rule, and recommended that we refer to 45 CFR 80.3(d) throughout and describe it rather than simply cite to it. Commenters asked us to exempt tribes and tribal health programs from § 92.207 and § 92.208 and make clear that tribal governments and health programs can limit insurance to their members. Commenters asserted that Purchased/Referred Care[26] programs should be permitted to limit coverage and be held harmless for discrimination on the basis of disability, age, or sex. One commenter recommended several additional changes to the rule to address its application to tribes, including excluding tribes and tribal health programs from the definitions of "covered entity" and "health program or activity," and excluding assistance to tribes and tribal health programs from the definition of "Federal financial assistance," along with other changes intended to achieve this purpose. Commenters stated that the changes proposed were necessary to reflect the full scope of protections in Federal law for tribal classifications and tribal sovereignty.

Response: 45 CFR 80.3(d) is not an exemption from coverage; it provides an exception to application of the prohibitions on race, color, and national origin discrimination when programs are authorized by Federal law to be restricted to a particular race, color, or national origin. The final rule incorporates that exception, and OCR will fully apply it, as well as other exemptions or defenses that may exist under Federal law. OCR intends to address any restrictions on application of the law to tribes in the context of individual complaints.

Comment: One tribal organization commented that tribal consultation on development of the rule was insufficient.

Response: We engaged in tribal consultation on the rule and, during that consultation, encouraged tribes and tribal organizations to submit comments on the proposed rule. Many did so. We believe that tribal consultation was sufficient.

Comment: One tribal organization stated that the reference to Indian Health Services (IHS) programs in the preamble was misleading, as some IHS programs are administered directly by tribes.

Response: We agree that the reference to IHS programs as an example of a federally administered program may be confusing, given that some IHS programs are administered directly by tribes. We have therefore changed the reference to "IHS programs" to "IHS programs administered by IHS."

Finally, we have added a severability clause to § 92.2, to indicate our intention that the rule be construed to give the maximum effect permitted by law to each provision. The rule provides that if a provision is held to be unenforceable in one set of circumstances, it should be construed to give maximum effect to the provision as applied to other persons or circumstances. Similarly, if a provision is held to be invalid or unenforceable, that provision should be severable from, and have no impact on the application of, the remainder of the rule. This provision is consistent with our interpretation of the Department's regulations implementing Title VI, Title IX, Section 504, and the Age Act.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.2, with two modifications. We are adding § 92.2(b)(2), which clarifies that if an application of Section 1557 requirements or this part would violate applicable Federal statutory protections for religious freedom and conscience, application of Section 1557 is not required. In addition, we have added § 92.2(c), containing a severability clause.

Relationship to Other Laws (§ 92.3)

In § 92.3 of the proposed rule, we proposed an explanation of the relationship of the rule to existing laws. Paragraph (a) proposed that Section 1557 is not intended to apply lesser standards for the protection of individuals from discrimination than the standards under Title VI, Title IX, Section 504, the Age Act, or the regulations issued pursuant to those laws. Consistent with the statute, paragraph (b) proposed that nothing in this part shall be interpreted to invalidate or limit the existing rights, remedies, procedures, or legal standards available to individuals aggrieved under other Federal civil rights laws or to supersede State or local laws that provide greater or equal protection against discrimination on the basis of race, color, national origin, sex, age, or disability. OCR explained that this intent is derived from Section 1557(b) of the ACA. In addition to the statutes that are cited directly in Section 1557(b), the proposed rule cited the Architectural Barriers Act of 1968,[27] the Americans with Disabilities Act of 1990 (ADA),[28] and Section 508 of the Rehabilitation Act of 1973 (Section 508).[29] We noted that these laws establish additional Federal civil rights protections for individuals with disabilities, and covered entities must be mindful that the obligations imposed by those laws apply to them independent of the application of Section 1557.

Summary of Regulatory Changes

OCR did not receive any comments on this provision. Therefore, for the reasons set forth in the proposed rule, we are finalizing the provisions as proposed in § 92.3 without modification.

Definitions (§ 92.4)

In § 92.4 of the proposed rule, we set out proposed definitions of various terms. The comments and our responses regarding § 92.4 are set forth below.

Disability. We proposed that the definition of "disability" be the same as the definition of this term in the Rehabilitation Act,[30] which incorporates the definition of disability in the ADA, as construed by the ADA Amendments Act of 2008.[31] In addition, we proposed to use the term "disability" in place of the term "handicap," which is used in some previous civil rights statutes and regulations. We provided that when we cross-reference other regulatory provisions, regulatory language that uses the term "handicap" shall mean "disability." We noted that this change in terminology does not reflect a change in the substance of the definition.

Comment: OCR received many comments related to the definition of disability. Several commenters asked OCR to provide additional guidance regarding the meaning of terms used within the definition of disability, including "physical or mental impairment," "major life activities," and "substantially limits." Other commenters asked OCR to include the term "chronic conditions" in the definition of disability or to add regulatory language to the definition of disability that creates a rebuttable presumption of disability for serious and chronic conditions. Still other commenters urged that OCR clarify that the definitions of disability and qualified individual with a disability are broad.

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[26] Funds under the Purchased/Referred Care program (formerly the Contract Health Services program) are used to supplement and complement other health care resources available to eligible American Indians and Alaska Natives. *See https://www.ihs.gov/newsroom/index.cfm/factsheets/purchasedreferredcare* (last updated Jan. 2015).

[27] 42 U.S.C. 4151–4157 (2012).

[28] 42 U.S.C. 12101 *et seq.* (codified as amended by the Americans with Disabilities Amendments Act of 2008, Public Law 110–325, 122 Stat. 3553 (2008)).

[29] 29 U.S.C. 794d.

[30] 29 U.S.C. 705(9)(B).

[31] Public Law 110–325, 122 Stat. 3553, § 4 (Sept. 25, 2008) (codified at 42 U.S.C. 12102).

Response: As noted in the proposed rule, the definition of "disability" is the same as the definition of this term in the Rehabilitation Act, which incorporates the definition of disability in the ADA, as construed by the ADA Amendments Act of 2008. Thus, the proposed rule incorporates the definition of "major life activities" and the construction of all of the terms and standards in the definition of "disability" set forth in the ADA Amendments Act. We believe this definition is appropriate and that OCR's intent, consistent with the ADA Amendments Act, to broadly interpret the term "disability" is clear. Whether a chronic condition is a disability will depend on whether it falls within the definition of disability in the final rule.

Comment: A few commenters asked for a definition of the term "reasonable modification." Other commenters asked for a definition of "accessibility," especially as that term pertains to electronic and information technology. Both sets of commenters suggested that adding definitions to the final rule would provide greater clarity to covered entities.

Response: OCR believes that defining the terms "reasonable modification" and "accessibility" in this rule is unnecessary, given the meaning that these terms have acquired in the long history of enforcement of Section 504 and the ADA in the courts and administratively. We intend to interpret both terms consistent with the way that we have interpreted these terms in our enforcement of Section 504 and the ADA and so decline to add these definitions to the final rule.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition of "disability" as proposed without modification.

Electronic and information technology. We proposed to define "electronic and information technology" to be consistent with 36 CFR 1194.4, the regulation implementing Section 508.

Comment: A few commenters recommended that OCR amend the definition of "electronic and information technology" to state that "electronic and information technology includes hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information." These commenters asserted that this definition, which is based on the definition of "health information technology" in the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009,[32] is preferable to the definition OCR proposed, which is based on the regulations implementing Section 508 that were promulgated in 2000. According to these commenters, the Section 508 definition is outdated and unduly narrow.

Response: As OCR stated in the Notice of Proposed Rulemaking, the definition of "electronic and information technology" is based on 36 CFR 1194.4, the regulation implementing Section 508. OCR believes that a definition of "electronic and information technology" that is consistent with the regulations implementing Section 508 will reduce the possibility of confusing or conflicting standards for covered entities. Moreover, the definition used in the HITECH Act was created for use in another context and is narrower in some respects than would be appropriate for Section 1557. However, OCR also shares the commenters' concern that the current definition found at 36 CFR 1194.4 is outdated and unduly narrow. Accordingly, OCR notes the recent Access Board proposal to replace the term "electronic and information technology" with an updated term and definition.

Specifically, on February 27, 2015, the Access Board proposed to revise and update its standards for electronic and information technology developed, procured, maintained, or used by Federal agencies covered by Section 508.[33] As part of these proposed revisions and updates, the Access Board announced that it intends to replace the term "electronic and information technology" in 36 CFR 1194.4 with the term "information and communication technology" and revise the definition significantly to make it broader and more compatible with modern technology.[34] OCR believes that the changes proposed by the Access Board will address the commenters' concerns. Therefore, and in order to maintain consistency with Section 508 while also addressing commenters' concerns that the definition proposed by OCR is outdated and unduly narrow, OCR has decided to change the definition of "electronic and information technology" in this rule so that it means the same as "electronic and information technology" as defined at 36 CFR 1194.4 or any term that replaces "electronic and information technology" at 36 CFR 1194.4. By citing to the regulation, OCR's definition will update with the Access Board's finalized rule.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we have changed the definition of "electronic and information technology" as proposed in § 92.4 to state that it means the same as "electronic and information technology," or any term that replaces it at 36 CFR 1194.4.

Employee health benefit program. We proposed that the term "employee health benefit program" means (1) health benefits coverage or health insurance provided to employees and/or their dependents established, operated, sponsored or administered by, for, or on behalf of one or more employers, whether provided or administered by entities including but not limited to a health insurance issuer, group health plan (as defined in the Employee Retirement Income Security Act of 1974 (ERISA), at 29 U.S.C. 1191b(a)), a third party administrator, or an employer; (2) an employer-provided or -sponsored wellness program; (3) an employer-provided health clinic; or (4) long term care coverage or insurance provided or administered by an employer, group health plan, third party administrator, or health insurance issuer for a covered entity's employees.

Comment: One commenter requested that OCR clarify that wellness programs that are separate from the employee health benefit plan are still an "employee health benefit program."

Response: We agree that wellness programs separate from an employee health benefit plan fall within the definition of an employee health benefit program. For example, an employer providing a gift card to each employee who receives a flu shot would be a wellness program within the meaning of the regulation, regardless of whether the wellness program is part of the employer's group health plan. We believe that the definition of "employee health benefit program" in the regulation makes this clear and thus are not adopting any revisions.

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[32] 42 U.S.C. 300jj(5).

[33] Architectural and Transportation Barriers Compliance Board, Information and Communication Technology (ICT) Standards and Guidelines. 80 FR 10880 (proposed Feb. 27, 2015) (to be codified at 36 FR pt. 1194).

[34] *See* 80 FR at 10905.

Comment: Some commenters requested that the definition of "employee health benefit program" specifically include excepted benefits, as defined for purposes of section 2791(c) of the Public Health Service Act (codified at 42 U.S.C. 300gg–91(c)), such as limited scope vision and dental insurance, disease-specific insurance and fixed-indemnity plans.

Response: We do not believe it is necessary to include an exhaustive list of types of benefits that would be included as an "employee health benefit program." The definition is broad enough to encompass any health benefit coverage or health insurance provided by an employer to its employees. Excepted benefits are further discussed infra under § 92.207.[35]

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 with minor technical revisions for clarity and for consistency with other parts of the final rule. We are making minor technical corrections to correct the ERISA citation to read "29 U.S.C. 1191b(a)(1)"; to clarify that the term "sponsored wellness program" is an "employer-sponsored" wellness program; to add "coverage" to the term "health insurance"; and to clarify that long term care coverage or insurance is provided or administered "for the benefit of an employer's employees."

Federal financial assistance. We proposed that the term "Federal financial assistance" includes grants, loans, and other types of assistance in accordance with the definition of "Federal financial assistance" in the regulations implementing Section 504 [36] and the Age Act,[37] and also specifically includes subsidies and contracts of insurance, in accordance with the statutory language of Section 1557. We also proposed that, consistent with OCR's enforcement of other civil rights authorities, the definition of Federal financial assistance does not include Medicare Part B.

An additional clause was added to the proposed regulatory provision, modeled on the definition of "Federal financial assistance" in the regulation implementing Title IX, which clarifies that in the educational context, Federal financial assistance includes wages, loans, grants, scholarships and other monies that are given to any entity for payment to or on behalf of students who are admitted to that entity or that are given directly to these students for payment to that entity.[38] In the proposed rule, we noted that in the health care context, Federal funds are provided to or on behalf of eligible individuals for premium tax credits and advance payments of premium tax credits and cost sharing reductions to ensure the affordability of health insurance coverage purchased through the Health Insurance Marketplaces. Thus, we noted that an issuer participating in any Health Insurance Marketplace℠ is receiving Federal financial assistance when advance payments of premium tax credits and/or cost sharing reductions are provided to or on behalf of any of the issuer's enrollees. We noted that a health care provider that contracts with such an issuer does not become a recipient of Federal financial assistance by virtue of the contract, but would be a recipient if the provider otherwise receives Federal financial assistance.

Comment: Many commenters objected to the statement in the preamble to the proposed rule that, consistent with OCR's enforcement of other civil rights authorities, the definition of Federal financial assistance does not include Medicare Part B. These commenters urged us to reverse this position, asserting that the historical rationale for the Department's position that Medicare Part B payments are not Federal financial assistance is inapplicable to Section 1557, which explicitly covers "contracts of insurance," and inconsistent with the current Medicare Part B payment scheme, in which providers are paid directly by the Medicare program instead of receiving payment from consumers who are then reimbursed by the Medicare program.

Response: OCR notes commenters' concerns, but does not believe that this rule is the appropriate vehicle to modify the Department's position.

Comment: We received many comments proposing that OCR revise the statement that a health care provider that contracts with an issuer does not become a recipient of Federal financial assistance by virtue of the contract. Commenters proposed that such a provider should become a recipient, and thus be covered by Section 1557, by virtue of the contract. The commenters expressed concern that under OCR's interpretation, such contractors would not be covered by the nondiscrimination requirements of Section 1557, thereby weakening the rule's effect.

Response: We do not believe the law supports the commenters' proposed across-the-board revision. Under the regulations implementing the statutes cited in Section 1557 and incorporated into this final rule, a recipient of Federal financial assistance is an entity to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipient. To determine whether an entity is a recipient of such assistance, courts look to the entity that Congress intended to assist or subsidize with those funds.[39] In this context, the contractor that is providing health services is not the intended recipient of a premium tax credit or cost-sharing reduction that an issuer receives and is therefore not covered under Section 1557 by virtue of the contract.

That said, there are numerous ways in which health services providers are recipients in their own right, whether the Federal financial assistance they receive comes through certain Medicare payments, Medicaid payments, or other funds from the Department. Therefore, instead of falling outside of Section 1557's purview, many health care providers will be subject to Section 1557 irrespective of their relationship to issuers receiving Federal financial assistance.

Moreover, nothing in the rule authorizes qualified health plan issuers or other issuers that are covered entities to contract away their own nondiscrimination obligations. Issuers must ensure that enrollees have equal access to health services provided by their coverage without discrimination on the basis of a prohibited criterion. Thus, even if individual providers do not independently receive Federal financial assistance, an issuer maintains a duty to ensure compliance with civil rights laws with respect to the treatment of its enrollees who use its networks.

Comment: One comment inquired whether the rule applies to programs in which the Department is an employer or when the Department offers benefits to Department employees.

Response: The Department is not covered as a federally assisted program, although the Department is covered by the rule as an administrator of health programs and activities. As to programs for Department employees, HHS is covered by employment discrimination laws, including Section 504 and Title VII, protecting Federal employees.

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[35] *See infra* discussion of excepted benefits under § 92.207.

[36] 45 CFR 84.3(h).

[37] 45 CFR 91.4.

[38] *See* 45 CFR 86.2(g)(1)(ii).

[39] *United States Dep't of Transport.* v. *Paralyzed Veterans of Amer.*, 477 U.S. 597, 604–06 (1986).

Comment: One commenter raised concerns over the applicability of the rule to doctors in solo medical practice, to doctors who practice in many settings, and to medical students receiving student loans. The commenter suggested that the health program or activity—not the solo practitioner as an individual—be required to comply with the rule, and requested that we clarify how a doctor can determine whether she is covered by the rule as she moves between practice settings. The commenter also expressed concern that a disproportionate number of younger doctors would be required to comply with the rule as recipients of Federal financial assistance in the form of student loans.

Response: We have not modified the final rule in response to these comments; however, we offer the following for clarification.

Section 1557 applies to a recipient of Federal financial assistance, whether a hospital, clinic, medical practice, or individual physician. Where, for example, a doctor is an employee of a hospital and the hospital receives Federal financial assistance, the hospital's program is the relevant health program or activity and it is the hospital that will be held accountable for discrimination under Section 1557. Where, similarly, a doctor contracts as an individual to provide health services at a free neighborhood clinic that receives Federal financial assistance, the clinic is the recipient of Federal financial assistance and liable for discrimination; the doctor is simply a contractor who is assisting the clinic in performing clinic services.

When a doctor has a private medical practice that receives Federal financial assistance, and the doctor, through her practice, works as an attending physician at a hospital, it is the medical practice that is providing the services at the hospital, and thus the practice that is liable for the discrimination.[40] Moreover, a solo medical practice (whether incorporated or not) that receives Federal financial assistance is a covered health program or activity.[41]

This approach is consistent with longstanding interpretations of civil rights law and the definition of a "recipient" of Federal financial assistance in the regulations implementing Section 504, Title VI, Title IX and the Age Act.

Finally, regarding receipt of student loan payments as Federal financial assistance, we clarify that the educational institution—not the student—is the recipient of the Federal financial assistance in that circumstance. Although the money is paid directly to the student, the university or other educational institution is the intended recipient. This is consistent with longstanding regulations implementing civil rights laws.

We made two clarifying changes to the definition of Federal financial assistance. In the proposed rule, we defined Federal financial assistance in subsection (1) as any type of arrangement in which the Federal government "provides or makes available" assistance. In subsection (2), we explained that Federal financial assistance "provided or administered by the Department" includes tax credits and other subsidies under Title I of the ACA and other funds providing health insurance coverage. Because our intention was to explain further the meaning of (1) as it applies to the Department in (2), we have changed (2) to use the same terms used in (1). Thus, (2) now refers to Federal financial assistance "provided or made available" by the Department.

In addition, in the proposed rule, subsection (2) provided that "Federal financial assistance provided or administered by the Department includes all tax credits under Title I of the ACA," as well as other funds extended by the Department for providing health coverage. Because the Department plays a role in administering tax credits under Title I of ACA but does not have primary responsibility for administering that credit, and to ensure that tax credits under Title I of the ACA are understood to be included within the definition, we have modified this subsection to state that Federal financial assistance the Department provides or makes available includes Federal financial assistance that the Department plays a role in providing or administering.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 with two modifications. The language of Subsection (2) of the definition has been modified to state that Federal financial assistance the Department provides or makes available includes Federal financial assistance that the Department plays a role in providing or administering.

Gender identity. We proposed that the term "gender identity" means an individual's internal sense of gender, which may be different from an individual's sex assigned at birth. We noted that the way an individual expresses gender identity is frequently called "gender expression," and may or may not conform to stereotypes associated with a particular gender. We also noted in the proposed rule that gender may be expressed through, for example, dress, grooming, mannerisms, speech patterns, and social interactions. For purposes of this part, we proposed that an individual has a transgender identity when the individual's gender identity is different from the sex assigned to that person at birth; an individual with a transgender identity is referred to in this part as a transgender individual. In the proposed rule, we noted that the approach taken in the proposed definition is consistent with the approach taken by the Federal government in similar matters.[42]

Comment: Several commenters suggested that we revise the definition of "gender identity" to reference non-binary identities in order to avoid ambiguity regarding application of the rule to individuals with non-binary gender identities. Some commenters noted that explicitly referencing non-binary identities in this definition would be important to avoid any doubt or misinterpretation given that gender has often been assumed to be binary, thus ignoring or marginalizing individuals with non-binary gender identities.

Response: OCR has made a slight change to the definition of "gender identity" to insert the clause "which may be male, female, neither, or a combination of male and female." The insertion of this clause helps clarify that those individuals with non-binary gender identities are protected under the rule.

Comment: Some commenters suggested that, consistent with previous court and Federal agencies' interpretations, OCR add "gender expression" to the definition of "gender identity" in order to make explicit our intention to protect individuals on this basis.

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[40] The hospital may also be responsible for discrimination by the doctor's practice that occurs at the hospital.

[41] The rule defines a "recipient" of Federal financial assistance to include an individual. See § 92.4.

[42] *See, e.g.,* U.S. Office of Personnel Management, Guidance Regarding the Employment of Transgender Individuals in the Federal Workplace (May 27, 2011), *https://www.opm.gov/policy-data-oversight/diversity-and-inclusion/reference-materials/gender-identity-Guidance/;* U.S. Office of Personnel Management, U.S. Equal Employment Opportunity Commission, U.S. Office of Special Counsel, U.S. Merit Systems Protection Board. Addressing Sexual Orientation and Gender Identity Discrimination in Federal Civilian Employment: A Guide to Employment Rights, Protections, and Responsibilities, p. 2 (June 2015), *http://www.opm.gov/LGBTGuide.*

Response: In the proposed and final rules' definition of gender identity, we explain that the way an individual expresses gender identity is frequently called "gender expression." OCR is clarifying that throughout this final rule, we interpret references to the term "gender identity" as encompassing "gender expression" and "transgender status." This position is consistent with the position taken by courts and Federal agencies.[43] These bases of discrimination are protected under the rule.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with three modifications. The first sentence of the definition of gender identity has been revised to reference the application of the rule to individuals with non-binary gender identities. OCR also made a technical edit to the last sentence to delete reference to the term "transgender identity." Finally, for clarity and consistency within the final rule, OCR has made a technical revision to the definition of gender identity to clarify that a transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth.

Health program or activity. We proposed that the term "health program or activity" means the provision or administration of health-related services or health-related insurance coverage and the provision of assistance in obtaining health-related services or health-related insurance coverage. We also proposed that, similar to the approach of the Civil Rights Restoration Act of 1987 (CRRA)[44] and except as specifically set forth otherwise in this part,[45] the term further includes all of the operations of an entity principally engaged in providing or administering health services or health insurance coverage, such as a hospital, health clinic, community health center, group health plan, health insurance issuer, physician's practice, nursing facility, or residential or community-based treatment facility. We proposed that OCR interpret "principally engaged" in a manner consistent with civil rights laws that use this term.

In the proposed rule, OCR stated that we intended the plural "health programs or activities" used in this part to have the same meaning as the term "health program or activity" in the singular. Similarly, we noted that the proposed part's use of "health programs and activities," a variation of "health program or activity," does not reflect a change in the substance of the definition of "health program or activity."

We proposed to interpret "health programs and activities" to include programs such as health education and health research programs. Because Federal civil rights laws already prohibit discrimination on the basis of race, color, national origin, disability, or age in all health research programs and activities that receive Federal financial assistance and prohibit discrimination on the basis of sex in all health research programs conducted by colleges and universities, we determined that the application of Section 1557 to health research should impose limited additional burden on covered entities.

However, OCR recognized that health research is conducted to answer scientific questions and improve health through the advancement of knowledge; it is not designed to result in direct health benefits to participants. We also recognized that research projects are often limited in scope for many reasons, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other nondiscriminatory considerations. Thus, we noted that criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.[46] OCR noted that we do not intend for inclusion of health research within the definition of health program or activity to alter the fundamental manner in which research projects are designed, conducted, or funded; nor did OCR propose to systematically review health research protocols.

We invited comment on programs and activities that should be considered health programs or activities.

Comment: We received comments requesting that we enumerate additional examples of a health program or activity, including but not limited to the Children's Health Insurance Program, all of the operations of Medicare, and student health plans.

Response: We agree that the Children's Health Insurance Program and other health programs operated by State and local governments are covered by the rule. We also agree that student health plans are a health program or activity covered by the rule, and note that all student health plans are covered by Title IX, as well as the other civil rights laws cited in Section 1557, if the institution receives Federal financial assistance.

Although the definition does not and could not specifically identify all health programs and activities covered by the rule (for example, we do not specifically mention programs that provide physical and/or behavioral health services, although they are health programs), we are adding the Children's Health Insurance Program and the Basic Health Program as additional examples, given their significance.

We decline to include "all the operations of Medicare" in the definition of health program or activity. While we agree that all parts of the Medicare program are a health program or activity, not all operations in the Medicare program constitute Federal financial assistance; as discussed above, Medicare Part B is excluded from the definition of Federal financial assistance under this rule and other HHS civil rights authorities.[47] Thus, we believe the proposed language could create confusion in determining the scope of the final rule.

Comment: Some commenters noted that OCR did not propose to define the term "health" in "health program and activity," and recommended that OCR use the definition of "health" adopted by the World Health Organization, which includes an individual's or population's physical, mental, or social well-being.[48]

Response: OCR declines to add a definition of "health," but interprets "health" to include physical and mental well-being.

Comment: Several commenters recommended that the rule apply only to the specific health program for which the entity receives Federal financial assistance, such as health insurance coverage sold through the Marketplace$^{\text{SM}}$, and not to other products and services provided outside the Marketplace^{SM} by issuers participating in the Marketplace^{SM}. These commenters stated that applying the rule to operations or products that are not the direct recipients of Federal financial assistance conflicts with the plain meaning of Section 1557.

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[43] *See Rumble* v. *Fairview Heath Servs.,* Civ. No. 14–cv–2037, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015) (Section 1557); *Schroer* v. *Billington,* 577 F. Supp.2d 293, 303 (D.D.C. 2008)(Title VII); *Macy* v. *Holder,* EEOC Appeal No. 0120120821, Agency No. ATF–2011–00751, 2012 WL 1435995, at *7 (Apr. 20, 2012), *http://www.eeoc.gov/decisions/0120120821%20Macy%20v%20DOJ%20ATF.txt* (Title VII).

[44] Public Law 100–259, 102 Stat. 28 (1988).

[45] Employee health benefits programs are discussed elsewhere in rule. *See infra* discussion of § 92.208.

[46] We note that it is not permissible for clinical researchers to consider "cost" of accommodating participants with disabilities as a reason to exclude them from participation.

[47] Medicare Parts A, C, and D all constitute Federal financial assistance. See *www.hhs.gov/civil-rights/for-individuals/faqs/what-qualifies-as-federal-financial-assistance/301/indeix.html.*

[48] *See http://www.who.int/about/definition/en/print.html.*(last visited Mar. 11, 2016).

Response: Section 1557 prohibits discrimination under "any health program or activity, any part of which is receiving Federal financial assistance. . . ." By applying the prohibition if "any part" of the health program or activity receives Federal financial assistance, the law provides that the term "health program or activity" must be interpreted in a manner that uniformly covers all of the operations of any entity that receives Federal financial assistance and that is principally engaged in health services, health insurance coverage, or other health coverage, even if only part of the health program or activity receives such assistance. This interpretation serves the central purposes of the ACA, and effectuates Congressional intent, by ensuring that entities principally engaged in health services, health insurance coverage, or other health coverage do not discriminate in any of their programs and activities, thereby enhancing access to services and coverage.

This approach is consistent with the approach Congress adopted in the CRRA, which amended the four civil rights laws referenced in Section 1557 and defines "program or activity" to mean "all of the operations of . . . an entire corporation, partnership, or other private organization, or an entire sole proprietorship . . . which is principally engaged in the business of providing," among other things, a range of social and health services. The CRRA establishes that the entire program or activity is required to comply with the prohibitions on discrimination if any part of the program or activity receives Federal financial assistance. The CRRA has been consistently applied since its enactment in 1988, and we believe that Congress adopted a similar approach with respect to the scope of health programs and activities covered by Section 1557. If any part of a health care entity receives Federal financial assistance, then all of its programs and activities are subject to the discrimination prohibition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are modifying the definition as proposed in § 92.4 to include the Children's Health Insurance Program and the Basic Health Program as additional examples of a health program or activity.

Individual with limited English proficiency. We proposed that the term "individual with limited English proficiency" codify the Department's longstanding definition reflected in guidance interpreting Title VI's prohibition of national origin discrimination, entitled Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons[49] (HHS LEP Guidance). Under the proposed definition, an individual whose primary language for communication is not English is considered an individual with limited English proficiency if the individual has a limited ability to read, write, speak or understand English. Accordingly, we proposed that an individual whose primary language for communication is not English, even if he or she has some ability to speak English, is an individual with limited English proficiency if the individual has a limited ability to read, write, speak or understand English.

Commenters addressing this definition overwhelmingly supported its codification from the HHS LEP Guidance to regulatory text. We did not receive suggested revisions to the wording of this definition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4, without modification.

Language assistance services. OCR proposed that the term "language assistance services" identify types of well-established methods or services used to communicate with individuals with limited English proficiency, including (1) oral language assistance; (2) written translation of documents and Web sites; and (3) taglines. We noted that a covered entity has flexibility to provide language assistance services in-house or through commercially available options. We declined to offer an exhaustive list of available methods. However, we proposed that paragraph (1) identify the following as available methods to communicate orally with individuals with limited English proficiency: Oral interpretation (in-person or remotely)[50] and direct communication through the use of bilingual or multilingual staff competent to communicate directly, in non-English languages using any necessary specialized vocabulary, with individuals with limited English proficiency.

We did not receive suggested revisions to the wording of this definition. Comments we received on the specific types of language assistance services mentioned in the definition are addressed in the relevant portions of the preamble to § 92.4 for those respective terms.

For clarity and consistency within the final rule, we are replacing several phrases in this definition with other terms to conform to changes made in other provisions of the final rule. First, in paragraph (1) regarding oral language assistance, we are adding the words "for an individual with limited English proficiency" after "qualified interpreter" because § 92.4 now defines "qualified interpreter for an individual with limited English proficiency" separately from a "qualified interpreter for an individual with a disability." Also, because § 92.4 defines "qualified bilingual/multilingual staff," we are replacing "bilingual or multilingual staff competent to communicate, in non-English languages using any necessary specialized vocabulary" with "the use of qualified bilingual/multilingual staff to communicate." In paragraph (2) regarding written translation, we are replacing the reference to written translation of "documents and Web sites" to "written content in paper or electronic form." Finally, because § 92.4 defines "qualified translator," we are adding "performed by a qualified translator" after "written translation."

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with technical revisions, as described in the preceding paragraph, to ensure consistency with other provisions of the final rule.

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[49] 68 FR 47311, 47313 (Aug. 8, 2003).

[50] We use the terms "oral interpretation" and "written translation" for clarity. The term "interpretation" used without the preceding descriptor of "oral" refers to the communication of information orally and the term "translation" used without the preceding descriptor of "written" refers to the communication of information in writing. *See, e.g.*, U.S. Dep't of Justice, Commonly Asked Questions and Answers Regarding Limited English Proficient (LEP) Individuals, *http://www.lep.gov/faqs/faqs.html#OneQ11* (last visited Mar. 15, 2016) (differentiating between interpreters and translators in FAQ 11); Interpreters and Translators, U.S. Dep't of Labor, Bureau of Labor Statistics, Occupational Outlook Handbook, 2014–15, *http://www.bls.gov/ooh/media-and-communication/interpreters-andtranslators.htm* (explaining that interpreters convert information in a spoken language and translators convert information in written language).

National origin. The proposed rule did not define the term "national origin."

Comment: A few commenters recommended defining "race, color, or national origin" to include "language" and "immigration status." Commenters asserted that "language" should be included to capture the application of national origin discrimination to individuals with limited English proficiency. As to immigration status, some commenters requested clarification that immigrants, and particularly non-U.S. citizens, are protected from discrimination on the basis of race, color, national origin, sex, age, or disability under Section 1557 and this part.

Response: In response to comments, we are providing further clarification on the scope of "national origin"; we determine it unnecessary to define "race" or "color." Thus, this final rule defines "national origin" consistent with the well-established definition of the term that the Equal Employment Opportunity Commission (EEOC) uses in its interpretation of Title VII of the Civil Rights Act of 1964.[51] This definition clarifies that national origin includes not only an individual's place of origin, but also his or her ancestor's place of origin, which reflects our intent that individuals born in the United States but who have an ancestry outside the United States are protected. This definition also clarifies that national origin includes an individual's manifestation of the physical, cultural, or linguistic characteristics of a national origin group.[52]

By contrast, we decline to include the term "immigration status" in the definition of "national origin." An individual's national origin is not the same as her citizenship or immigration status, and neither Title VI nor Section 1557 explicitly protects individuals against discrimination on the basis of citizenship or immigration status. However, as under Title VI, Section 1557 and this part protect individuals present in the United States, whether lawfully or not, who are subject to discrimination based on race, color, national origin, sex, age, or disability. Moreover, OCR considers an immigrant or noncitizen to state a cognizable national origin discrimination claim under Title VI,[53] Section 1557, and this part when the claim alleges that a covered entity's use of a facially neutral policy or practice related to citizenship or immigration status has a disparate impact on individuals of a particular national origin group.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term "national origin" in § 92.4 to include an individual's manifestation of the physical, cultural, or linguistic characteristics of a national origin group as well as an individual's or her ancestor's place of origin.

On the basis of sex. We proposed that the term "on the basis of sex" includes, but is not limited to, discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity.

We noted that Section 1557 extends the grounds for discrimination found in the nondiscrimination laws cited in the statute (*i.e.*, race, color, national origin, sex, age, or disability) to certain health programs and activities. We noted that the HHS Title IX regulation explicitly includes discrimination on the basis of pregnancy as a form of discrimination on the basis of sex, and we proposed that the definition in this section mirror that regulation.[54]

We noted that the proposed inclusion of sex stereotyping reflects the Supreme Court's holding in *Price Waterhouse* v. *Hopkins*,[55] and that discrimination based on stereotypical notions of appropriate behavior, appearance or mannerisms for each gender constitutes sex discrimination.

We proposed that discrimination on the basis of sex further includes discrimination on the basis of gender identity. We noted that like other Federal agencies,[56] HHS has previously interpreted sex discrimination to include discrimination on the basis of gender identity.[57] We also noted that courts, including in the context of Section 1557, have recognized that sex discrimination includes discrimination based on gender identity.[58] Thus, we proposed to adopt formally this well-accepted interpretation of discrimination "on the basis of sex."

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[51] 29 CFR 1606.1 (defining "national origin discrimination").

[52] In addition, courts have adopted this principle. *See, e.g., Bennun* v. *Rutgers State Univ.*, 941 F.2d 154, 173 (3d Cir. 1991), *cert. denied,* 502 U.S. 1066 (1992) (stating that an individual's birth in a foreign country where another culture predominates, immersion in that country's ways of life, and speaking the native language in one's home, are sufficient to identify the individual as part of a national origin group); *Fragante* v. *City and County of Honolulu,* 888 F.2d 591, 595–96 (9th Cir. 1989), *cert. denied,* 494 U.S. 1081 (1990) (stating that accent and national origin are inextricably intertwined in many cases); *Gutierrez* v. *Mun. Court of Southeast Jud. Dist., Los Angeles Cnty.*, 838 F.2d 1031, 1039 (9th Cir. 1988 *vac'd and rem,* 490 U.S. 1016 (1989)(stating that "[b]ecause language and accents are identifying characteristics, "rules which have a negative effect on bilinguals, individuals with accents, or non-English speakers, may be mere pretexts for intentional national origin discrimination"). A member of a religious group states a cognizable national origin discrimination claim under Title VI and Section 1557 and this part when that discrimination is based on a religious group's shared ancestry or its physical, cultural, and linguistic characteristics rather than its members' religious practice. *See* Letter from Thomas Perez, Assistant Attorney Gen., Civil Rights Div., U.S. Dep't of Justice to Russlynn Ali, Assistant Sec'y for Civil Rights, Office for Civil Rights, U.S. Dep't of Educ. Re: Title VI and Coverage of Religiously Identifiable Groups, at 2 (Sept. 8, 2010), *https://www.justice.gov/sites/default/files/crt/legacy/2011/05/04/090810_AAG_Perez_Letter_to_Ed_OCR_Title%20VI_and_Religiously_Identifiable_Groups.pdf.*

[53] *See* Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Ariz. Health Care Cost Containment System & the Ariz. Dep't of Econ. Sec., OCR Transaction Nos. 10–117078 & 10–117875 (2015), *http://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/Arizona/vra.pdf* [hereinafter HHS OCR VRA with AZ Agencies] (resolving cognizable complaints of national origin discrimination under Title VI following implementation of a State law requiring State employees, in the administration of public benefits programs, to report "discovered violations of federal immigration law" to U.S. Immigration and Customs Enforcement).

[54] *See* 45 CFR 86.40(b) (prohibiting discrimination on the basis of "pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom").

[55] 490 U.S. 228, 250–51 (1989).

[56] *See* 5 CFR 300.102(c), 300.103(c), 300.103(c), 315.806(d), 335.103(b)(1), 537.105(d), 900.603(e) (U.S. Office of Personnel Management regulations providing that discrimination on the basis of sex includes discrimination on the basis of gender identity); Directive 2014–02, U.S. Dep't of Labor, Office of Fed. Contract Compliance Programs, § 5 (Aug. 19, 2014), *http://www.dol.gov/ofccp/regs/compliance/directives/dir2014_02.html;* Statement of Interest of the United States, *Jamal* v. *SAKS & Co.*, No. 4:14–CV–2782 (S.D. Tex. Jan. 26, 2015) *https://www.justice.gov/sites/default/files/crt/legacy/2015/02/27/jamalsoi.pdf;* Statement of Interest of the United States, *Tooley* v. *Van Buren Pub. Sch.*, No. 2:14–cv–13466–AC–DRG (E.D. Mich. Feb. 24, 2015) *https://www.justice.gov/sites/default/files/crt/legacy/2015/02/27/tooleysoi.pdf;* Memo from Eric Holder, Att'y Gen., to U.S. Att'ys & Heads of Dep't Components (Dec. 18, 2014), *https://www.justice.gov/opa/pr/attorney-general-holder-directs-department-include-gender-identity-under-sex-discrimination;* U.S. Dep't of Educ., Questions and Answers on Title IX and Sexual Violence, p. B–2, *http://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf; Macy,* 2012 WL 1435995, at *11.

[57] *See* Letter from Leon Rodriguez, Director, U.S. Dep't of Health & Human Servs., Office for Civil Rights, to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights (Jul. 12, 2012), *https://www.nachc.com/client/OCRLetterJuly2012.pdf.*

[58] *See, e.g., Rumble* v. *Fairview Heath Servs.,* Civ. No. 14–cv–2037, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015) (Section 1557) (order denying motion to dismiss); *Barnes* v. *City of Cincinnati,* 401 F.3d 729, 737 (6th Cir.), *cert. denied,* 546 U.S. 1003 (2005)(Title VII); *Smith* v. *City of Salem, Ohio,* 378 F.3d 566, 575 (6th Cir. 2004) (Title VII); *Schroer* v. *Billington,* 577 F.Supp.2d 293, 304 (D.D.C. 2008) (Title VII). *But see Johnston* v. *Univ. of Pittsburgh,* 97 F.Supp.3d 657, 671 (W.D. Pa. 2015) (appeal docketed, No. 1502922) (3d Cir. Apr. 24, 2015) (holding that an individual treated in accordance with sex assigned at birth has not been discriminated against on the basis of sex under Title IX).

OCR stated that as a matter of policy, we also support banning discrimination in health programs and activities on the basis of sexual orientation. We noted that current law is mixed on whether existing Federal nondiscrimination laws prohibit discrimination on the basis of sexual orientation as a part of their prohibitions on sex discrimination. However, we further noted that a recent U.S. EEOC decision, *Baldwin* v. *Department of Transportation,*[59] concluded that Title VII's prohibition of discrimination "on the basis of sex" includes sexual orientation discrimination because discrimination on the basis of sexual orientation necessarily involves sex-based considerations.

We proposed that the final rule reflect the current state of nondiscrimination law, and we sought comment on the best way of ensuring that this rule includes the most robust set of protections supported by the courts on an ongoing basis.

Comment: Several commenters commended OCR's inclusion of discrimination not only on the basis of pregnancy, but also on the basis of pregnancy-related procedures or conditions in the definition of "on the basis of sex" and noted that such a position is consistent with existing civil rights statutes. Other commenters noted concern that the inclusion of the phrase "termination of pregnancy" in the definition of "on the basis of sex" will be interpreted as requiring the provision or coverage of, or referral for, pregnancy termination, and urged OCR to state explicitly that neither Section 1557 nor the regulation imposes such a requirement.

Response: The definition of "on the basis of sex" established by this rule is based upon existing regulation and previous Federal agencies' and courts' interpretations that discrimination on the basis of sex includes discrimination on the basis of pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom.

Additionally, the final rule balances an individual's right to access health programs and activities free from discrimination with protections for religious beliefs and practices. As we explained in the preamble to the proposed rule and have reiterated here, this rule does not displace existing protections afforded by, for example, Federal provider conscience laws and RFRA. Again, with respect to concerns about potential conflicts between provisions of the final rule and individuals' or organizations' sincerely held religious beliefs, we refer to the discussion at § 92.2 in this preamble. With respect to abortion, moreover, nothing in Section 1557 displaces the ACA provisions regarding abortion, including but not limited to the provision that no qualified health plan offered through a Marketplace may discriminate against an individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions;[60] provisions that state that nothing in the ACA shall be construed to require a qualified health plan to provide coverage of abortion as an essential health benefit;[61] and the provision permitting States to prohibit abortion coverage in qualified health plans and restricting the use of Federal funding for abortion services.[62]

Comment: A significant number of commenters commended our inclusion of gender identity and sex stereotyping in the definition of "on the basis of sex" and noted that the inclusion is consistent with a growing body of legal precedent. Some commenters suggested OCR add transgender status and gender expression in the definition of "on the basis of sex" in order to make explicit our intention to protect individuals on these bases, consistent with previous court and Federal agency interpretations.

Conversely, a few commenters opined that the inclusion of gender identity discrimination as a form of discrimination on the basis of sex was based on erroneous interpretations of Title IX legislative history because Congressional intent to ban sex discrimination was based only on the biological classifications of males and females, not gender identity. A few commenters thought that OCR's reliance on previously adopted Federal agencies' interpretations was weak and unpersuasive and that the reliance on cases arising under Federal civil rights laws other than Title IX was misplaced, further pointing to a few recent court decisions under Title IX that rejected claims that discrimination on the basis of sex includes discrimination on the basis of gender identity.

A few commenters also suggested that the inclusion of "gender identity" as a prohibited basis of discrimination on the basis of sex may infringe upon individual patients' constitutional right to privacy by requiring those patients to participate in sex-specific programs or activities with a "non-biological" male or female and additionally contravenes employees' and faith-based organizations' religious beliefs by forcing them to participate in services affirming gender identity in violation of their religious convictions.

Response: The definition of "on the basis of sex" established by this rule is based upon existing regulation and previous Federal agencies' and courts' interpretations that discrimination on the basis of sex includes discrimination on the basis of gender identity and sex stereotyping. While OCR appreciates the commenters' request that we add transgender status and gender expression to the definition of "on the basis of sex," we do not believe that it is necessary to add these terms to the definition. As previously stated, we encompass these bases in the definition of "gender identity"; thus, references to "gender identity" include "gender expression" and "transgender status." Because the definition of "on the basis of sex" includes gender identity, further reference to transgender status or gender expression here is superfluous.

OCR also believes that its inclusion of gender identity is well grounded in the law and disagrees with those commenters who argued to the contrary. As the Supreme Court made clear in *Price Waterhouse* v. *Hopkins,* in prohibiting sex discrimination, Congress intended to strike at the entire spectrum of discrimination against men and women resulting from sex stereotypes.[63] Courts after *Price Waterhouse* interpret Title VII's protections against discrimination on the basis of sex as encompassing not only "sex," or biological differences between the sexes, but also "gender" and its manifestations.[64] In essence, *Price Waterhouse* thus rejects the reasoning, and vitiates the precedential value, of earlier Federal appellate court decisions that limited Title VII's coverage of "sex" to the anatomical and biological characteristics of sex. Moreover, courts frequently look to case law interpreting other civil rights provisions, including Title VII, for guidance in interpreting Title IX.[65]

OCR's approach accords with well-accepted legal interpretations adopted by other Federal agencies and courts.

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[59] U.S. Equal Employment Opportunity Comm'n Appeal No. 0120133080, Agency No. 2012-24738-FAA-03 (July 15, 2015), *http://www.eeoc.gov/decisions/0120133080.txt.*

[60] 42 U.S.C. 18023(b)(4).

[61] 42 U.S.C. 18023(b)(1)(A).

[62] 42 U.S.C. 18023.

[63] 490 U.S. at 251 (citations omitted).

[64] *See, e.g., Smith* v. *City of Salem, Ohio,* 378 F.3d. 566, 573–74 (6th Cir. 2004).

[65] *See, e.g., Wolfe* v. *Fayetteville, Ark. Sch. Dist.,* 648 F.3d 860, 864 n.4 (8th Cir. 2011); *Weinstock* v. *Columbia Univ.,* 224 F.3d 33, 42 n.1 (2d Cir. 2000), *cert. denied,* 540 U.S. 811 (2003).

For example, Title IX Guidance issued by the U.S. Department of Education generally requires recipients of federal financial assistance to treat transgender students consistent with their gender identity.[66] The Fourth Circuit reversed a lower court decision dismissing the Title IX sex discrimination claim of a transgender student prohibited from using the school bathroom consistent with his gender identity, holding that the Department of Education's interpretation of its regulation was not plainly erroneous, and thus was entitled to controlling weight.[67]

The fact that there may be circumstances in which it is permissible to make sex-based distinctions is not a license to exclude individuals from health programs and activities for which they are otherwise eligible simply because their gender identity does not align with other aspects of their sex, or with the sex assigned to them at birth. The Department has a responsibility to ensure that health programs and activities of covered entities are carried out free from such discrimination.

To the extent that privacy considerations may be relevant in an anti-discrimination analysis, OCR will consider these interests in the context of individual complaints. We note, however, that at least one court has rejected a claim that an individual's legal right to privacy is violated simply by permitting another person access to a sex-specific program or facility that corresponds to their gender identity.[68] With respect to concerns about potential conflicts between provisions of the final rule and individuals' or organizations' sincerely held religious beliefs, we refer to the discussion at § 92.2 in this preamble.

Comment: A few commenters recommended that OCR clarify that the prohibition on sex discrimination extends to discrimination on the basis of the presence of atypical sex characteristics and intersex traits (*i.e.,* people born with variations in sex characteristics, including in chromosomal, reproductive, or anatomical sex characteristics that do not fit the typical characteristics of binary females or males). At least one commenter noted that this clarification is necessary because intersex people may face discrimination when medical providers or insurance companies follow policies which deem certain medical procedures available to only one sex, thereby excluding intersex people who may be registered under another sex.

Response: We agree with the commenters that the prohibition on sex discrimination extends to discrimination on the basis of intersex traits or atypical sex characteristics. OCR intends to apply its definition of "on the basis of sex" to discrimination on these bases.

Comment: Many commenters requested that OCR explicitly state in the rule that Section 1557's prohibition of discrimination on the basis of sex includes discrimination on the basis of sexual orientation. Other commenters asserted that Section 1557 did not intend to protect against sexual orientation discrimination and that OCR does not have authority to include this basis because no Federal appellate court has interpreted Title IX's or Title VII's ban on sex discrimination to protect same-sex relationships or conduct.

Response: As we noted in the preamble to the proposed rule, we support a prohibition on discrimination based on sexual orientation as a matter of policy. We believe that it is critical to meeting the goals of Section 1557 and, more broadly, the ACA, to ensure equal access to health care and health coverage. Indeed, these policy goals are reflected in the increasing number of actions taken by Federal agencies to ensure that lesbian, gay, and bisexual individuals are protected from discrimination. For example, CMS regulations bar discrimination on the basis of sexual orientation by Health Insurance Marketplaces and issuers offering qualified health plans;[69] Medicare regulations prohibit the restriction of visitation rights in hospitals based on sexual orientation (or gender identity);[70] and the Social Security Administration is now processing Medicare enrollments for same-sex spouses.[71] Court decisions have, moreover, repeatedly made clear that individuals and couples deserve equal rights regardless of their sexual orientation.[72]

The preamble to the proposed rule stated our policy position and noted that "[t]he final rule should reflect the current state of nondiscrimination law, including with respect to prohibited bases of discrimination" while seeking comment on the issue. While the preamble observed that no Federal appellate court has concluded to date "that Title IX's prohibition of discrimination 'on the basis of sex'—or Federal laws prohibiting sex discrimination more generally—prohibits sexual orientation discrimination," it also noted recent court decisions that have prohibited discrimination in cases involving allegations of discrimination relating to an individual's sexual orientation on the grounds that such discrimination is discrimination on the basis of sex stereotyping.

Price Waterhouse v. *Hopkins*[73] is the foundational decision that underlies these legal developments. Though *Price Waterhouse* did not involve an allegation of discrimination based on an individual's sexual orientation, the Supreme Court recognized in that case that unlawful sex discrimination occurs where an individual is treated differently based on his or her failure to conform to gender-based stereotypes about how men or women should present themselves or behave. The Department of Justice has therefore taken the position that a well-pled complaint alleging discrimination against a gay employee because of his failure to conform to sex stereotypes states a viable sex discrimination claim under Title VII.[74] When a covered entity discriminates against an individual based on his or her sexual orientation, the entity may well rely on stereotypical notions or expectations of how members of a certain sex should act or behave. These stereotypes are precisely the type of gender-based assumptions prohibited by *Price Waterhouse.*[75]

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[66] U.S. Dep't of Education, Office for Civil Rights, Questions and Answers in Title IX and Single Sex Elementary and Secondary Classes and Extra-Curricular Activities, (2014), *http://www2.ed.gov/about/offices/list/ocr/docs/faqs-title-ix-single-sex-201412.pdf.*

[67] .*G. ex rel. Grimm* v. *Gloucester Cty. Sch. Bd.,* No. 15–2056, 2016 WL 1567467 at * 6 (4th Cir. 2016).

[68] *See e.g., Crosby* v. *Reynolds,* 763 F. Supp. 666 (D. Me. 1991) (requiring female prisoner to share a cell with a transgender woman violated no clearly established constitutional right); *cf. Cruzan* v. *Special Sch. Dist., #1,* 294 F.3d 981 (8th Cir. 2002) (per curiam) (teacher's assertion that her personal privacy was invaded when school permitted a transgender woman to use women's restroom was not cognizable under employment discrimination law).

[69] 45 CFR 155.120(c)(1)(ii); 156.200(e).

[70] 42 CFR 482.13(h)(3).

[71] *http://www.medicare.gov/sign-up-change-plans/same-sex-marriage.html* (last visited Mar. 11, 2016).

[72] For example, in 1996, the Supreme Court struck down an amendment to the Colorado constitution that prohibited the State government from providing any legal protections to gay, lesbian, and bisexual individuals. *Romer* v. *Evans,* 517 U.S. 620 (1996). And, just last year, the Supreme Court ruled in *Obergefell* v. *Hodges,* 135 S. Ct. 2584 (2015), that states may not prohibit same-sex couples from marrying and must recognize the validity of same-sex couples' marriages.

[73] 490 U.S. 228 (1989).

[74] *See* Def.'s Renewed Mot. to Dismiss at 18–19, *Terveer* v. *Billington,* No. 1:12–cv–1290, ECF No. 27 (D.D.C. Mar. 21, 2013).

[75] *See, e.g., Deneffe* v. *SkyWest, Inc.,* No. 14–cv–00348, 2015 WL 2265373, at * (D. Colo. May 11, 2015); *Terveer* v. *Billington,* 34 F. Supp. 3d 100, 116 (D.D.C. 2014); *Boutillier* v. *Hartford Pub. Schs.,*

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Based on this understanding, some courts have recognized in the wake of *Price Waterhouse* that discrimination "because of sex" includes discrimination based on sex stereotypes about sexual attraction and sexual behavior[76] or about deviations from "heterosexually defined gender norms."[77] For example, a recent district court decision in the Ninth Circuit held that the distinction between discrimination based on gender stereotyping and discrimination based on sexual orientation is artificial, and claims based on sexual orientation are covered by Title VII and Title IX, not as an independent category of claims separate from sex and gender stereotyping, but as sex or gender discrimination.[78]

In addition, in *Baldwin* v. *Department of Transportation* the EEOC concluded that Title VII's prohibition of discrimination "because of sex" includes sexual orientation discrimination because discrimination on the basis of sexual orientation necessarily involves sex-based considerations.[79] The EEOC relied on several theories to reach this conclusion: A plain reading of the term "sex" in the statutory language, an associational theory of discrimination based on "sex," and the gender stereotype theory announced in *Price Waterhouse*.

For all of these reasons, OCR concludes that Section 1557's prohibition of discrimination on the basis of sex includes, at a minimum, sex discrimination related to an individual's sexual orientation where the evidence establishes that the discrimination is based on gender stereotypes. Accordingly, OCR will evaluate complaints alleging sex discrimination related to an individual's sexual orientation to determine whether they can be addressed under Section 1557.

OCR has decided not to resolve in this rule whether discrimination on the basis of an individual's sexual orientation status alone is a form of sex discrimination under Section 1557. We anticipate that the law will continue to evolve on this issue, and we will continue to monitor legal developments in this area. We will enforce Section 1557 in light of those developments and will consider issuing further guidance on this subject as appropriate.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 without modification.

Qualified bilingual/multilingual staff. In the proposed rule, we proposed to define "language assistance services" to include, as a type of oral language assistance, the use of staff members who are "competent to communicate, in non-English languages using any necessary specialized vocabulary, directly with individuals with limited English proficiency."[80] The proposed rule did not define the term "qualified bilingual/multilingual staff."

Comment: Some commenters observed that as an alternative to providing oral interpretation, many covered entities rely on staff members to serve individuals with limited English proficiency in their respective primary languages. According to these commenters, covered entities mistakenly assume that staff members who possess a rudimentary familiarity with at least one non-English language are competent to provide oral language assistance for the covered entity's health program or activity. Commenters asked us to require covered entities to assess the proficiency of staff members who communicate directly with individuals with limited English proficiency in their respective primary languages.

Response: In response to commenters' observations, we have defined the term "qualified bilingual/multilingual staff" in § 92.4 to clarify the knowledge, skills, and abilities that a staff member must demonstrate for a covered entity to designate that staff member to provide effective oral language assistance.[81] Specifically, qualified bilingual/multilingual staff must demonstrate to the covered entity that they are proficient in English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology, and are able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary language. An individual who meets the definition of "qualified bilingual/multilingual staff" does not necessarily qualify to interpret or translate for individuals with limited English proficiency within the meaning of this rule.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term "qualified bilingual/multilingual staff" in § 92.4 to clarify that such an individual must be proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology, and must be able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.

Qualified interpreter. We proposed that the term "qualified interpreter" means an individual who has the characteristics and skills necessary to interpret for an individual with a disability, for an individual with limited English proficiency, or for both. In the proposed rule, the language in paragraph (1), applicable for interpreting for an individual with a disability, is the same as language in the regulations implementing Titles II and III of the ADA, at 28 CFR 35.104 and 36.104, respectively. The language in paragraph (2) of the proposed rule, applicable for interpreting for an individual with limited English proficiency, reflects a synthesis of the attributes, described in the Department's LEP Guidance, that are necessary for an individual to interpret competently and effectively under the circumstances and thus to provide the effective oral language assistance services required under the law.[82] We noted that the fact

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2014 WL 4794527 at *2 (D. Conn. 2014); *Koren* v. *The Ohio Bell Tel. Co.*, 894 F. Supp.2d 1032, 1037–38 (N.D. Ohio. 2012); *Heller* v. *Columbia Edgewater Country Club*, 195 F. Supp.2d 1212, 1224, *adopted*, 195 F. Supp.2d 1216 (D. Or. 2002); *Centola* v. *Potter*, 183 F. Supp.2d 403, 410 (D. Mass. 2002).

[76] *See Videckis and White* v. *Pepperdine Univ.*, No. 15–00298, 2015 WL 8916764 (C.D. Cal. Dec. 15, 2015) (denying motion to dismiss).

[77] *Isaacs* v. *Felder*, No. 2:13 cv 693, 2015 WL 6560655, at * 9 (M.D. Ala. Oct. 29, 2015) (internal quotation marks omitted).

[78] *Videckis*, 2015 WL 8916764. Prior circuit court decisions have drawn such distinctions. *See, e.g., Dawson* v. *Bumble & Bumble*, 398 F.3d 211, 218 (2d Cir. 2005); *Vickers* v. *Fairfield Med. Ctr.*, 453 F.3d 757, 763 (6th Cir. 2006).

[79] U.S. Equal Employment Opportunity Comm'n Appeal No. 0120133080, Agency No. 2012–24738–FAA–03 (July 15, 2015), *http://www.eeoc.gov/decisions/0120133080.txt* (finding that sexual orientation is inseparable from and inescapably linked to sex and thus that an allegation of discrimination based on sexual orientation is necessarily an allegation of sex discrimination).

[80] *See* 80 FR at 54176, 54216.

[81] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47317 (stating that the covered entity may provide oral language assistance through bilingual staff members that are "competent to communicate directly with [limited English proficient] persons in their language").

[82] *See* HHS LEP Guidance, 68 FR at 47311, 47316 (explaining that an individual's proficiency in another language, knowledge of specialized terminology, and adherence to interpreter ethics are considerations in determining competency to interpret); *id.* at 47317–18, 47323 (discussing why family members, friends, and ad hoc interpreters may not be competent to interpret); The language is also consistent with the approach we have taken in our Title VI enforcement efforts. *See, e.g.,* Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Mee Memorial Hosp., OCR Transaction

that an individual has above average familiarity with speaking or understanding a language other than English does not suffice to make that individual a qualified interpreter for an individual with limited English proficiency.

We proposed that the definition of "qualified interpreter" includes criteria regarding interpreter ethics, including maintaining client confidentiality. As we stated in the proposed rule, bilingual or multilingual staff members may not possess competence in the skill of interpreting nor have knowledge of generally accepted principles of interpreter ethics. A qualified bilingual/multilingual nurse who is competent to communicate in Spanish directly with Spanish-speaking individuals may not be a qualified interpreter for an individual with limited English proficiency if serving as an interpreter would pose a conflict of interest with the nurse's treatment of the patient.

Comment: A few commenters suggested that OCR amend the definition of qualified interpreter to require interpreters to be licensed by State law in the State where the entity is providing services. Other commenters suggested that OCR require interpreters to be certified by a national nonprofit certification organization.

Response: We recognize the commenters' concerns regarding licensure and certification, but we decline to accept these recommendations. Although OCR considers licensure and certification as evidence that an interpreter is qualified, licensure and certification are neither necessary nor sufficient evidence of qualification for the following reasons.[83] First, OCR does not wish to unduly narrow the pool of qualified interpreters available to a covered entity by requiring certification or licensure; many interpreters who are currently unlicensed and uncertified are competent to translate at a level that would meet the requirements of Section 1557 and this part.

Second, there are several organizations, both for-profit and non-profit, that offer certification programs for interpreters. Even if the credentialing standards developed by those organizations currently satisfy Section 1557 requirements, the organizations' standards are subject to change and there is no assurance that such standards would consistently meet the standards of Section 1557. In addition, other national credentialing organizations could be established whose standards failed to meet the requirements of the law. Similar issues with respect to new and changing standards could also arise in the State licensing context.

Third, there are factors unrelated to credentials that could cause OCR to determine that an interpreter is unqualified. For example, if an interpreter has not practiced in a long time or is late to appointments, the interpreter might be unqualified regardless of the interpreter's State or non-profit credentials. For all of these reasons, we decline to amend the definition of qualified interpreter in the ways these commenters proposed.

Comment: We received many comments in support of the proposed rule's inclusion of a definition of "qualified interpreter." Some commenters, however, requested that we define a qualified interpreter who interprets for individuals with limited English proficiency separately from a qualified interpreter who interprets for individuals with disabilities, noting that there are significant differences between the provision of oral interpretation services in these two contexts. Other commenters suggested broadening the lexicon an interpreter must possess to be a qualified interpreter for a particular covered entity's health program. Specifically, commenters suggested that an interpreter's required knowledge and abilities to be "qualified" should include not only knowledge of any necessary specialized vocabulary but also knowledge of terminology and phraseology.

Response: We have modified § 92.4 to provide separate definitions of "qualified interpreter for an individual with limited English proficiency" [84] and "qualified interpreter for an individual with a disability." We agree that it is important to account for the qualifications necessary for interpreting for each set of individuals. In addition, we added the words "terminology" and "phraseology" in both definitions to align the final rule's description of the requisite knowledge, skills, and abilities an interpreter must possess with those recognized within the field.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we no longer define "qualified interpreter" as one term. We are using the content from proposed paragraphs (1), (1)(i), and (2) to create a separate definition for "qualified interpreter for an individual with a disability" and similarly use the content from proposed paragraphs (1) and (1)(ii) to create a separate definition for "qualified interpreter for an individual with limited English proficiency." For both definitions, we added "terminology and phraseology" to the lexicon a qualified interpreter in both contexts must possess.

Qualified translator. The proposed rule did not use or define the term "qualified translator."

Comment: We received a significant number of comments recommending that the proposed rule define "qualified translator." Commenters explained that bilingual individuals do not necessarily possess the skill of translating or the knowledge of specialized terminology to be able to translate written documents from English to another language. Similarly, a qualified interpreter for an individual with limited English proficiency may not possess the knowledge, skills, and abilities to translate, as the skill of interpreting is different from the skill of translating.[85]

Response: In response to commenters' recommendations, we are adding the term "qualified translator" to the final rule. The final rule defines qualified translator as someone who translates effectively, accurately, and impartially; adheres to generally accepted translator ethics principles; and is proficient in both written English and at least one other written non-English language, including any necessary specialized vocabulary, terminology and phraseology. We agree with commenters that even if an individual meets the definition of "qualified bilingual/multilingual staff" or "qualified interpreter for an individual with

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Nos. 12–143846, 13–1551016 & 13–153378, pt. II.J. (2014) [hereinafter HHS OCR VRA with Mee Memorial Hospital], *http://www.hhs.gov/ocr/civilrights/activities/agreements/mee.html* (defining qualified interpreter); Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Montgomery County Dep't of Soc. Servs., OCR Transaction No. 08–79992, pts. II.E (defining qualifications of an "interpreter" under the agreement), IV.H (requiring timely, competent language assistance); & IV.L (identifying interpreter standards) [hereinafter HHS OCR VRA with Montgomery County DSS], *http://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/examples/limited-english-proficiency/MCDSS-resolution-agreement/index.html.*

[83] *See* HHS LEP Guidance, 68 FR at 47316 ("Competency to interpret, however, does not necessarily mean formal certification as an interpreter, although certification is helpful.").

[84] We note that this final rule uses the terms "qualified interpreter for an individual with limited English proficiency" interchangeably with "qualified interpreter for the individual with limited English proficiency" and "qualified interpreter to an individual with limited English proficiency." The preposition and article used within the phrase do not represent a change in meaning.

[85] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47316; Int'l Medical Interpreters Assoc., Guide on Medical Translation 4 (Jan. 2009), *http://www.imiaweb.org/uploads/pages/438.pdf.*

limited English proficiency" under this rule, that individual does not necessarily possess the knowledge, skills, or abilities to translate written content in paper or electronic form used in a covered entity's health programs or activities.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term "qualified translator" in § 92.4 to set out the competencies an individual must have to translate written content in paper or electronic form in the covered entity's health programs or activities.

Sex stereotypes. We proposed that the term "sex stereotypes" refers to stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. We noted that these stereotypes can include expectations that gender can only be constructed within two distinct opposite and disconnected forms (masculinity and femininity), and that gender cannot be constructed outside of this gender construct.

Comment: Commenters suggested that OCR revise the definition of "sex stereotypes" because, while accurate in describing the types of assumptions that may motivate discrimination against non-binary individuals, the definition is cumbersome and may not be readily understood by persons not familiar with the issue. Several commenters expressed concern that the proposed language might be interpreted as limiting sex discrimination based on sex stereotyping to only include discrimination based on gender identity. Commenters suggested affirming in the final rule that any form of sex discrimination on the basis of sex stereotypes constitutes sex discrimination, whether or not it also constitutes discrimination on the basis of gender identity. Some commenters requested that OCR provide examples illustrating discrimination based on sex stereotypes that can form the basis of prohibited sex discrimination.

Several commenters suggested that OCR clarify the definition of "sex stereotypes" to address the relationship between sex stereotypes and sexual orientation. In this regard, commenters suggested that OCR revise the definition of "sex stereotypes" to add that "sex-stereotypes also include gendered expectations related to the appropriate roles of men and women, such as the expectation that women are primary caregivers, and aspects of an individual's sexual orientation, such as the sex of an individual's sexual or romantic partners."

Response: We have added a reference in the regulatory text to make clear that sex stereotypes include gendered expectations related to the appropriate roles of a certain sex.[86] With regard to sexual orientation, we refer commenters to the discussion in the preamble addressing the definition of "on the basis of sex."[87]

Comment: Some commenters stated that the proposed definition of sex stereotypes is unprecedented in its breadth with no legal authority to support the proposition that individuals who claim to identify with non-binary genders constitute a protected class under Title IX or any other Federal law. Commenters suggested that it is impossible for an individual to have a non-binary gender identity.

Response: OCR has adopted the approach taken by the Federal government and numerous courts in similar matters—that sex stereotypes encompass not only stereotypes concerning the biological differences between the sexes, but also include stereotypes concerning gender norms.[88] As stated in the preamble to the proposed rule and clarified in the final rule, OCR recognizes that sex stereotypes can include the expectation that individuals consistently identify with only one of two genders (male or female), and that they act in conformity with the gender-related expressions stereotypically associated with that gender. Sex stereotypes can also include a belief that gender can only be binary and thus that individuals cannot have a gender identity other than male or female. OCR recognizes that an individual's gender identity involves the interrelationship between an individual's biology, gender, internal sense of self and gender expression related to that perception; thus, the gender identity spectrum includes an array of possible gender identities beyond male and female.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with the following modifications: We have clarified that sex stereotypes can be based on expectations about gender roles.

Taglines. In the proposed rule, we defined taglines as short statements written in non-English languages to alert individuals with limited English proficiency to the availability of language assistance services, free of charge, and how the services can be obtained.[89] We did not receive comments with suggested revisions to the wording of this definition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 without modification.

Assurances Required (§ 92.5)

In § 92.5, we proposed that each entity applying for Federal financial assistance, each issuer seeking certification to participate in a Health Insurance Marketplace ^{SM}, and each state seeking approval to operate a State-based Marketplace ^{SM} be required to submit an assurance that its health programs and activities will be operated in compliance with Section 1557. We noted that the regulations implementing Title VI, Title IX, Section 504, and the Age Act all require similar assurances. We modeled the assurance, duration of obligation, and covenants language on the Section 504 regulation.[90] We also proposed to revise the Assurance of Compliance HHS–690 Form to include all civil rights laws, including Section 1557, with which covered entities must comply.

The comments and our responses regarding § 92.5 are set forth below.

Comment: Several commenters recommended that OCR require covered entities to collect data on race, ethnicity, language, sex, gender, gender identity, sexual orientation, disability, and age. These commenters suggested that covered entities should be required to assess the populations they serve so that the covered entities can better plan how to meet the needs of those populations.

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[86] *See, e.g., Chadwick* v. *Wellpoint,* Inc., 561 F.3d 38, 45 (1st Cir. 2009) (adverse employment action based on assumption that women are responsible for family caregiving and will perform their jobs less well as a result of caregiving responsibilities is discrimination based on sexual stereotypes in violation of Title VII). *See also Glenn* v. *Brumby,* 663 F.3d 1312 (11th Cir. 2011) ("These instances of discrimination against plaintiffs because they fail to act according to socially prescribed gender roles constitute discrimination under Title VII according to the rationale of *Price Waterhouse."*).

[87] *See* discussion § 92.4, *supra.*

[88] *See Price Waterhouse,* 490 U.S. at 251; *Smith,* 378 F.3d. at 573 (citations omitted).

[89] The HHS LEP Guidance, *supra* note 49, 68 FR at 47320, describes the practice of tagging non-English statements on the front of common documents, such as "brochures, booklets, and in outreach and recruitment information" informing individuals with limited English proficiency of the availability of language assistance services.

[90] 45 CFR 84.5.

The commenters also urged that OCR require annual submission of the data to OCR and develop standards to address training on data collection, privacy protections, safeguarding, voluntary reporting by patients, and supporting analyses based on multiple variables.

Response: OCR agrees that data collection is an important tool that can help covered entities to better serve their communities, and encourages covered entities to regularly evaluate the impact of the services they provide on different populations. However, OCR declines to require data collection as part of the assurances required under Section 1557. The Department collects data pursuant to Section 4302 of the ACA, and OCR has access to these data. In addition, OCR has the authority to require covered entities to collect data and to provide OCR access to information under §§ 92.302 and 92.303 of this part,[91] and will exercise this authority as needed and appropriate under particular circumstances in the future. With respect to recipients and State-based Marketplaces, §§ 92.302(a) and 92.302(b) incorporate the procedural provisions in the Title VI and the Age Act implementing regulations regarding enforcement actions under this part. Pursuant to these procedural provisions, when a recipient or State-based Marketplace SM fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may find noncompliance with Section 1557 and initiate appropriate enforcement procedures, including beginning the process for fund suspension or termination and taking other action authorized by law. OCR has inserted a new subsection (c) to § 92.302 to clarify that it has that it has this authority, and the text that was previously found at § 92.302(c) has been moved to the new § 92.302(d).

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.5 without modification.

Remedial Action and Voluntary Action (§ 92.6)

In § 92.6, we proposed provisions addressing remedial action and voluntary action by covered entities. In paragraph (a), we proposed that a recipient or State-based Marketplace SM that has been found to have discriminated on any of the bases prohibited by Section 1557 be required to take remedial action as required by the Director to overcome the effects of that discrimination. We proposed that similar to recipients and State-based Marketplaces, the Department, including the Federally-facilitated Marketplaces, is also obligated to address discrimination, but is subject to a different remedial process than recipients and State-based Marketplaces. In paragraph (b), we proposed to permit but not require all covered entities to take voluntary action in the absence of a finding of discrimination to overcome the effects of conditions that result or resulted in limited participation by persons based on race, color, national origin, sex, age, or disability. The provisions at §§ 92.6(a) and (b) are modeled after the Title VI, Title IX, Section 504, and Age Act regulations.

The comments and our responses regarding § 92.6 are set forth below.

Comment: One commenter requested that OCR specifically list the remedial actions available to OCR as well as the circumstances under which such remedial actions will be taken.

Response: In the discussion of enforcement mechanisms and procedures in the preamble to the proposed rule, OCR identified the range of enforcement tools available to OCR. However, it would not be feasible to specify the circumstances in which specific remedial actions would be taken. OCR evaluates each situation on a case-by-case basis and may use different remedial actions in different cases. In all cases, OCR attempts to achieve compliance and, in our experience, this approach has been successful.

Comment: One commenter requested clarification of the word "control" in the part of the regulation that states that where a recipient exercises "control" over a recipient that has discriminated, the Director may require both entities to take remedial action. Another commenter suggested that OCR only pursue remedial action against the entity actually found to have discriminated against an individual and not against the controlling entity.

Response: OCR declines to further define the word "control" as used in the regulation. This term has appeared in civil rights regulations enforced by OCR for many years, and its meaning has been established over time. OCR also declines to limit its authority to pursue remedial action with respect to an entity that exercises control over an entity that has discriminated. This too is longstanding authority under OCR's other authorities, and in OCR's experience, controlling entities that are recipients often play an important role in securing appropriate action to remedy discrimination.

Comment: One commenter suggested that there be limitations on the uses of remedial action. Specifically, the commenter stated that OCR should require remedial action only on behalf of individuals who either (1) applied to participate but were unable to participate due to alleged discrimination; or (2) had been participants and were subject to alleged discrimination. The commenter asserted that without such limitations, covered entities could be unfairly exposed to claims by individuals who would not have been participants notwithstanding any alleged discrimination.

Response: OCR does not believe that limiting the availability of remedial action as suggested is appropriate. It would not be consistent with Section 1557's and OCR's commitment to eliminating discrimination in all parts of a program or activity and remedying discrimination, where necessary, with respect to harmed individuals.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.6 without modification.

Designation of Responsible Employee and Adoption of Grievance Procedures (§ 92.7)

In § 92.7, we proposed requirements for each covered entity that employs 15 or more persons to designate a responsible employee to coordinate the entity's compliance with the rule and adopt a grievance procedure. Many entities covered by Section 1557 and this part are already required to designate a compliance coordinator and have a written process in place for handling grievances with respect to disability discrimination in all programs and activities or sex discrimination in education programs or activities.[92]

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[91] Section 92.302 incorporates provisions of the Title VI implementing regulation with respect to enforcement actions concerning discrimination on the basis of race, color, national origin, sex, age, or disability. Those provisions authorize OCR to collect reports from recipients as necessary to determine compliance. Section 92.303 incorporates provisions in the Section 504 implementing regulation with respect to discrimination on the basis of prohibited criteria in health programs or activities administered by the Department. Those provisions authorize OCR to initiate actions as necessary to ensure compliance.

[92] Under Section 504, a recipient of Federal financial assistance with 15 or more employees must designate at least one individual to coordinate the covered entity's compliance with Section 504's

Continued

In paragraph (a), we proposed that a covered entity that employs 15 or more persons be required to designate at least one employee to coordinate compliance with the requirements of the rule. We noted that a covered entity that has already designated a responsible employee pursuant to the regulations implementing Section 504 or Title IX may use that individual to coordinate its efforts to comply with Section 1557.

In paragraph (b), we proposed that a covered entity that employs 15 or more persons be required to adopt a grievance procedure that incorporates appropriate due process standards and allows for the prompt and equitable resolution of complaints concerning actions prohibited by Section 1557 and this part. We noted that a covered entity that already has a grievance procedure addressing claims of disability discrimination that meets the standards established under the Section 504 regulation may use that procedure to address disability claims under Section 1557. In addition, we noted that covered entities may use that procedure to address all other Section 1557 claims, provided that the entity modifies the procedure to apply to race, color, national origin, sex, and age discrimination claims.

We proposed that for the Department, including Federally-facilitated Marketplaces, OCR will be deemed the responsible employee. In addition, we proposed that OCR's procedures for addressing complaints of discrimination on the grounds protected under Section 1557 will be deemed grievance procedures for the Department, including for the Federally-facilitated Marketplaces.

In the proposed rule, OCR invited comment on whether all covered entities, not only those that employ 15 or more persons, should be required to designate responsible employees and establish grievance procedures.

The comments and our responses regarding § 92.7 are set forth below.

Comment: Some commenters opposed inclusion of proposed § 92.7, arguing that it is unnecessary and costly and has few benefits because discrimination in health programs and activities does not exist. Other commenters urged that Federal regulation in this area constrains covered entities' flexibility to decide how to address individuals' complaints of discrimination. Specifically, these commenters encouraged OCR to allow covered entities to retain existing internal grievance processes, leverage grievance processes within State agencies or within other entities, or develop new grievance procedures.

Response: We recognize commenters' concerns, but we disagree with commenters regarding the necessity of proposed § 92.7. To promote the effective and efficient implementation of Section 1557 and this part, it is necessary for covered entities with 15 or more employees to identify at least one individual accountable for coordinating the covered entity's compliance and to have a written process in place for handling grievances. We recognize that not all covered entities are organized and operate in the same way. Thus, we do not prescribe who in the covered entity must serve as the responsible employee—nor do we prohibit combining this function with other duties so long as there is no conflict of interest.

In addition, we disagree with commenters that proposed § 92.7 is costly, limits covered entities' flexibility, or conflicts with existing internal or State-mandated grievance procedures. As we stated in the proposed rule, recipients of Federal financial assistance with 15 or more employees, as well as the State-based Marketplaces, could increase the responsibilities of an already-designated coordinator to include the coordination of compliance with Section 1557 and this part.[93] These entities could also increase the scope of the existing grievance procedures required under Section 504 and the ADA to accommodate complaints of discrimination addressing all bases prohibited under Section 1557. Moreover, nothing in the rule bars a covered entity from combining the grievance procedure required under Section 1557 with procedures it uses to address other grievances, including those unrelated to individuals' civil rights. As described in the Regulatory Impact Analysis of the proposed rule[94] and reiterated in the Regulatory Impact Analysis to this final rule, the costs associated with these requirements are estimated to be minimal.

Comment: Some commenters stated that the final rule should specify minimum regulatory requirements for the grievance procedure required in § 92.7(b). Such minimum requirements would include, for instance: Timeframes for filing, resolving, and issuing written decisions regarding complaints; an appeal process; notice regarding retaliation protections; and clarification that no person needs to exhaust a covered entity's grievance procedure prior to filing a Section 1557 complaint with OCR. These commenters urged OCR to adopt regulatory requirements, instead of a model grievance procedure only, stating that a model policy alone is insufficient to ensure that an entity's grievance procedure provides meaningful rights and protections.

Response: We understand the commenters' concerns, but we decline to promulgate minimum standards for the content of the grievance procedure required in § 92.7(b); such an approach would be too prescriptive. Because Section 1557 and this part cover a variety of types of entities, we want to preserve flexibility for entities to adapt the rule's requirements to their own health programs and operational capacity, so long as the rules result in the prompt and equitable resolution of complaints. However, to provide covered entities an example of how to structure a grievance procedure that affords individuals appropriate procedural safeguards and provides for the prompt and equitable resolution of complaints, we have included a sample procedure as Appendix C. We disagree with commenters that a sample grievance procedure is insufficient; rather, a sample grievance procedure provides guidance to covered entities while also preserving their flexibility. In response to commenters' suggestion that we note that an individual need not exhaust a covered entity's grievance procedure prior to filing a Section 1557 complaint, we clarify that no such exhaustion requirement exists, as reflected in the sample grievance procedure included as Appendix C to the final rule.

Comment: Many commenters supported the alternate approach that would require covered entities with fewer than 15 employees to comply with § 92.7. These commenters reasoned that requiring all covered entities to designate a coordinator and establish a grievance procedure would give each entity the internal mechanisms to resolve compliance issues earlier and informally, allowing them to potentially avoid a formal investigation by OCR. Accordingly, these commenters asserted that the importance of extending

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prohibition of disability discrimination and must have a written process in place for handling grievances. 45 CFR 84.7(a). Under Title IX, a recipient of Federal financial assistance must designate at least one individual to coordinate the recipient's compliance with Title IX's prohibition of sex discrimination with respect to the recipient's education program or activity and must have a written process in place for handling grievances. 45 CFR 86.8(a). Under Title II of the ADA, an entity with 50 or more employees must designate at least one individual to coordinate the covered entity's compliance with Title II's prohibition of disability discrimination and must have a written process in place for handling grievances. 28 CFR 35.107(a).

[93] *See* 80 FR 54172, 54202 (Sept. 8, 2015).

[94] *Id.*

required compliance with § 92.7 to covered entities with fewer than 15 employees justified the anticipated additional expense of compliance.

Some commenters observed that the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule already requires many entities covered by Section 1557 and this part to implement grievance policies and identify compliance coordinators, regardless of the number of employees of the entity.[95] The commenters suggested that the implementation of these requirements under the HIPAA Privacy Rule has given entities with fewer than 15 employees covered by both the HIPAA Privacy Rule and Section 1557 and this part the experience necessary to implement the similar requirements of § 92.7. Because many of the covered entities with fewer than 15 employees, such as most health care providers receiving Federal financial assistance, are subject to the HIPAA Privacy Rule, commenters asserted that extending the requirements of § 92.7 to covered entities with fewer than 15 employees would impose a limited burden.

Conversely, some commenters suggested that compliance with § 92.7 would be too time consuming and costly for covered entities with fewer than 15 employees. These commenters explained that due to the small number of employees, small covered entities may have difficulty identifying an unbiased third-party employee to investigate and respond to grievances. For instance, commenters noted that it is not uncommon for the chief physician or other professional to serve as the compliance coordinator for a small covered entity, but that such a role would be inappropriate if that individual was the subject of a grievance. These commenters also observed that requiring a covered entity to handle internal grievances under Section 1557 might expose the entity to the risk of civil liability, because Section 1557 allows for private enforcement. These commenters recommended that OCR allow small covered entities flexibility in determining when to defer to outside counsel or other independent, unbiased third parties to address grievances and thus mitigate their liability risk.

Response: We decline to extend the requirements of § 92.7 to covered entities with fewer than 15 employees. Although we recognize the benefits that extension of the requirements of § 92.7 would generate, we conclude that the costs, which would be borne by small entities, likely outweigh the benefits. Although many covered entities with fewer than 15 employees may have already identified a compliance coordinator and implemented a grievance policy to comply with the HIPAA Privacy Rule, extending the requirements of § 92.7 to such entities would create additional costs, as entities would need to revise their existing policies and retrain compliance coordinators.

Although we decline to extend the requirement of § 92.7 to covered entities with fewer than 15 employees, nothing in the final rule bars a covered entity with fewer than 15 employees from designating an employee to coordinate compliance with Section 1557 and this part or from adopting and implementing a grievance procedure. As we stated in the proposed rule, in OCR's experience, the presence of a coordinator and grievance procedure enhances the covered entity's accountability and helps bring concerns to prompt resolution, oftentimes prior to an individual bringing a private right of action.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.7 with one technical modification in § 92.7(a): We replaced the reference to the "Office for Civil Rights" with "Director," as § 92.4 defines "Director" to mean the Director of the Department's OCR. We have also added a sample grievance procedure as Appendix C to the final rule to provide covered entities an example of a grievance procedure that meets the requirements of § 92.7(b).

Notice Requirement (§ 92.8)

In § 92.8, OCR proposed that each covered entity take initial and continuing steps to notify beneficiaries, enrollees, applicants, or members of the public of individuals' rights under Section 1557 and this part and of covered entities' nondiscrimination obligations with respect to their health programs and activities. We modeled this section generally after the notice requirements found in regulations implementing Title VI, Title IX, Section 504, and the Age Act, which require covered entities to have a notice in place.[96]

Paragraphs (a)(1)–(7) of proposed § 92.8 identify the components of the notice. Specifically, paragraph (a)(1) proposed that the notice include that the covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability.

Paragraph (a)(2) proposed that the notice include a statement that the covered entity provides auxiliary aids and services, free of charge, in a timely manner, to individuals with disabilities, when such aids and services are necessary to provide an individual with a disability an equal opportunity to benefit from the entity's health programs or activities. Paragraph (a)(3) proposed that the notice state that the covered entity provides language assistance services, free of charge, in a timely manner, to individuals with limited English proficiency, when those services are necessary to provide an individual with limited English proficiency meaningful access to a covered entity's health programs or activities.

Paragraph (a)(4) proposed that the notice include information on how an individual can access the aids and services referenced in (a)(2) and (a)(3).

Paragraph (a)(5) proposed that the notice provide contact information for the responsible employee coordinating compliance with Section 1557 and this part, where such a responsible employee is required by § 92.7(a).

Paragraph (a)(6) proposed that the notice state that the covered entity has a grievance procedure where such a grievance procedure is required by § 92.7(b), and information on how to file a grievance.

Paragraph (a)(7) proposed that the notice provide information on how to file a complaint with OCR. We noted that inclusion of this requirement ensures that covered entities inform individuals about the enforcement mechanisms outside of the covered entity's internal process.

Proposed paragraph (b) stated that within 90 days of the effective date of this part, each covered entity shall post the notice required in § 92.8(a) in English, consistent with paragraph (f) of this section.

Paragraph (c) proposed that the Director shall make available a sample notice. We provided that covered entities may use this sample notice or may develop their own notices that convey the information in paragraphs (a)(1) through (7).

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[95] *See* 45 CFR 164.520(b)(1)(vi) and § 164.530(a)(1)(ii) (requires designation of "contact person or office who is responsible for receiving complaints under this subsection" and the provision of a notice "that contains a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint," respectively.)

[96] 45 CFR 80.6(d) (requiring recipients to provide notice of individuals' rights under Title VI), 84.8(a)–(b) (requiring recipients to provide notice of individuals' rights under Section 504), 86.9(a)–(c) (requiring notice of individuals' rights under Title IX), 91.32 (requiring recipients to provide notice of individuals' rights under the Age Act).

OCR invited comment on whether the proposed rule should permit covered entities to combine the content of the notice with the content of other notices that covered entities may be required to disseminate or post under Federal laws. OCR further invited comment on what steps covered entities may or should take to ensure that notices that combine the content required in § 92.8(a)(1)–(7) with other required notices do so without compromising the intent of § 92.8 to inform individuals of their civil rights under Section 1557 and this part. OCR also invited comment on whether the final rule should allow the notice to be modified for publications and other communication vehicles that may not have sufficient space to accommodate the full notice.

Paragraph (c) also proposed that the Director shall translate the sample notice into the top 15 languages spoken by individuals with limited English proficiency nationally and make the translated notices available to covered entities electronically and in any other manner the Director determines appropriate. We encouraged covered entities to post one or more of the translated notices that the Director provides and to make the notice available in non-English languages other than those provided by the Director. OCR sought comments on requiring, rather than merely encouraging, covered entities to post one or more of the notices in the most prevalent non-English languages frequently encountered by covered entities in their geographic service areas.

With regard to the proposal that the Director provide translations of the sample notice, we described that we selected the top 15 languages spoken by individuals with limited English proficiency nationally as a data driven policy.[97] We noted that we plan to review U.S. Census Bureau data as newer data become available to determine if and when the top 15 languages spoken nationally by individuals with limited English proficiency change, warranting the Director to make available notices in additional non-English languages.

Paragraph (d) proposed that within 90 days of the effective date of this part, each covered entity shall post, consistent with paragraph (f) of this section, taglines in at least the top 15 languages spoken nationally by individuals with limited English proficiency. We requested comment on a sample tagline in Appendix B to the proposed rule.

Paragraph (e) proposed that the Director shall make available taglines in the top 15 languages spoken nationally by individuals with limited English proficiency for use by covered entities. OCR proposed this approach to maximize efficiency and economies of scale by enabling covered entities to receive the benefits of having multi-language taglines available without incurring the associated translation costs.

In paragraph (f), we proposed that covered entities must post the English-language notice required in § 92.8(a) and taglines required in § 92.8(d) in a conspicuously-visible font size in: Significant publications or significant communications targeted to beneficiaries, enrollees, applicants, or members of the public, which may include patient handbooks, outreach publications, or written notices pertaining to rights or benefits or requiring a response from an individual; in conspicuous physical locations; and in a conspicuous location on the home page of a covered entity's Web site. We sought comment on the scope of significant publications and significant communications.

We noted that covered entities that distribute significant publications or significant communications will need to update these publications to include the notice required in § 92.8(a) and taglines required in § 92.8(d). However, we proposed allowing entities to exhaust their current stock of hard copy publications rather than requiring a special printing of the publications to include the new notice.

We stated that covered entities may satisfy the requirement to post the notice on the covered entity's home page by including a link in a conspicuous location on the covered entity's home page that immediately directs the individual to the content of the notice elsewhere on the Web site. Similarly, we stated with regard to the requirement to post taglines that covered entities can comply by posting "in language" Web links, which are links written in each of the 15 non-English languages posted conspicuously on the home page that direct the individual to the full text of the tagline indicating how the individual may obtain language assistance services. For instance, a tagline directing an individual to a Web site with the full text of a tagline written in Haitian Creole should appear as "Kreyòl Ayisien" rather than "Haitian Creole."

In the proposed rule, we invited comment on a State-based methodology for identifying the languages in which covered entities would be required to post taglines and for which the OCR Director would be required to translate the notice. We explained that the top 15 languages spoken by individuals with limited English proficiency nationally can differ from the languages spoken most frequently by individuals within the areas served by covered entities' health programs and activities. Thus, we invited comment on a requirement for entities to make taglines available in the top 15 languages spoken State-wide, rather than nationwide, by individuals with limited English proficiency. This threshold aligns with Federal regulations governing the Health Insurance Marketplaces and qualified health plan issuers.[98]

To reduce the burden on covered entities, proposed subsection (g) of this section stated that a covered entity's compliance with § 92.8 satisfies the notice requirements under HHS's Title VI, Section 504, Title IX, and Age Act regulations. We requested comment on this proposal.

The comments and our responses regarding § 92.8 are set forth below.

Comment: Some commenters suggested that we revise the information required in § 92.8(a)(1)–(7) regarding the notice of individuals' rights. For instance, some commenters suggested that we specify that Section 1557 prohibits discrimination on the basis of "national origin, including primary language and immigration status" and "sex, including pregnancy, gender identity, sex stereotypes, or sexual orientation. . . ." These commenters asserted that the addition of these terms would more completely reflect the scope of protected classes under Section 1557. A few commenters recommended that the notice inform individuals of any religious accommodations or exemptions that the covered entity has received from compliance with civil rights laws and explain the services that the covered entity will and will not provide as a result of any religious exemptions or accommodations. Finally, a few commenters recommended revising §§ 92.8(a)(2) and (a)(3) to more closely parallel each other. For example, these commenters recommended that we list examples of language assistance services in paragraph (a)(3) and add a reference to providing meaningful access for persons with disabilities in paragraph (a)(2) of § 92.8.

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[97] *See* 80 FR 54179 (describing the methodology used in the proposed rule).

[98] *See* 45 CFR 155.205(c)(2)(iii)(A). This regulation, which requires taglines on certain documents and Web site content in at least the top 15 languages spoken State-wide by individuals with limited English proficiency is not the only tagline requirement with which qualified health plan issuers must comply. Qualified health plan issuers must comply with another tagline requirement applicable to group health plans and health insurance issuers, which requires taglines, on certain notices and on a health plan's summary of benefits and coverage, in languages in which 10% of individuals with limited English proficiency county-wide are exclusively literate. *See, e.g.*, 45 CFR 147.136(e)(2)(iii), (e)(3) (HHS regulations); 29 CFR 2590.715–2719(e)(2)(iii), (3) (DOL regulations for group health plans and health insurance issuers that are not grandfathered health plans).

Response: We decline to incorporate the suggestions made with regard to § 92.8(a)(1). The final rule defines the terms "on the basis of sex" and "national origin" in § 92.4, which is sufficient to define the scope of these protected classes as used in § 92.8(a)(1) and in Appendix A.[99] We are concerned that replicating the regulatory definitions of "on the basis of sex" and "national origin" in § 92.8(a)(1) and across-the-board in the final rule would dilute the concise, targeted message of the nondiscrimination statement and reduce the value of identifying the core bases on which discrimination is prohibited. Further, replicating the definitional text of these bases in § 92.8(a)(1) but not throughout the final rule may cause unnecessary confusion regarding the scope of discrimination prohibited by Section 1557 and this part. Accordingly, we decline to make the suggested revisions and are removing the terms "including sex stereotypes and gender identity" from the sample notice in Appendix A. OCR intended the nondiscrimination statement in § 92.8(a)(1) to convey covered entities' overarching nondiscrimination obligations in a simple and streamlined manner, as the notice requirements do in regulations implementing Title VI, Title IX, Section 504, and the Age Act.[100] The notice requirement of the Title IX implementing regulations does not require recipients of Federal financial assistance to identify exclusions from Title IX's application or exceptions to discrimination prohibited under Title IX.[101] Moreover, under the final rule, the availability of a religious exemption will depend on an analysis of the particular situation; thus, it would be difficult for an entity to state that it was exempt for all purposes. Accordingly, this final rule preserves the simplicity of the nondiscrimination statement consistent with other Federal civil rights laws.

We have revised § 92.8(a)(3) to list examples of language assistance services to parallel § 92.8(a)(2), which lists examples of auxiliary aids and services. We decline to modify the standards in paragraphs (a)(2) and (a)(3) because "meaningful access" is not the proper standard used in Section 504 for ensuring effective communication for individuals with disabilities.

Finally, as we stated in the proposed rule, Appendix A to part 92 is a sample notice. Covered entities are free to draft their own notices that convey the content in § 92.8(a)(1)–(7).

Comment: We received many comments addressing practical concerns about the size and length of required notices and taglines. Some commenters supported giving covered entities the flexibility to combine the content of the notice in § 92.8(a)(1)–(7) with other notices required under other Federal laws. For instance, a few comments stated that the State-based Marketplaces should be allowed to combine the content of the notice in § 92.8(a) with disclosures required by Federal regulations governing the Health Insurance Marketplaces at 45 CFR 155.230. Conversely, some commenters strongly opposed the idea of combining the content of the notice required in § 92.8(a) with other notices, reasoning that the combination, and likely modification, of the notice's content would diminish the clear message of the notice.

Some commenters expressed concern that posting the notice and the taglines in a "conspicuously-visible font size" as proposed in § 92.8(f)(1) and a "conspicuous physical location" as proposed in § 92.8(f)(1)(ii) would occupy prohibitive amounts of space for covered entities operating in small physical spaces, such as pharmacies. These commenters suggested that OCR permit covered entities operating in smaller physical spaces to post taglines in fewer than 15 non-English languages. Other commenters requested clarification from OCR on what constitutes a "conspicuous physical location" in § 92.8(f)(ii) and "conspicuously visible font size" in § 92.8(f)(1).

A number of commenters recommended that the final rule require covered entities to post the notice of individuals' rights—and not just taglines—in non-English languages.

Response: We intend to provide covered entities some flexibility to implement the requirements of § 92.8 in the manner that they determine meets the standards of this section while also reducing burden.

For instance, we will permit covered entities to combine the content of the notice in § 92.8(a)(1)–(7) with the content of other notices, such as notices required under other Federal civil rights laws. The content of the combined notice still must clearly convey the information required in § 92.8 (a)(1)–(7) and must separately meet any applicable notice requirements under relevant legal authorities. For instance, the regulations implementing Title IX and Section 504 require that a recipient provide a notice of individuals' rights to employees and applicants for employment.[102] Because this final rule is limited in its application to employment, it may not be sufficient for an entity covered by Title IX, Section 504, and Section 1557 and this part to rely on a notice conveying the content required in § 92.8(a)(1)–(7) as meeting its notice obligations under the regulations implementing Section 504 and Title IX. Accordingly, proposed paragraph (g), which is now re-designated as paragraph (h) of this final rule, no longer treats an entity's compliance with particular paragraphs of § 92.8 as constituting compliance with the notice provisions of other Federal civil rights authorities.

Specifically, § 92.8(h) now clarifies that covered entities may combine the content of the notice in § 92.8(a)(1)–(7) with the content of other notices as long as the combined notice clearly informs individuals of their civil rights under Section 1557 and this part. In addition to having flexibility with respect to combining notices, covered entities also have flexibility in determining the exact size and location of notices and taglines within their facilities as long as they do not compromise the intent of § 92.8 to clearly inform individuals of their civil rights under Section 1557 and this part.

The touchstone by which we will assess whether a covered entity's provision of notice and taglines is effective is whether the content is sufficiently conspicuous and visible that individuals seeking services from, or participating in, the health program or activity could reasonably be expected to see and be able to read the information.

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[99] An individual's national origin is not the same as her citizenship or immigration status, and neither Title VI nor Section 1557 explicitly protects individuals against discrimination on the basis of citizenship or immigration status. However, as under Title VI, Section 1557 and this part protect individuals present in the United States, whether lawfully or not, who are subject to discrimination based on race, color, national origin, sex, age, or disability. *See* discussion *supra* note 53.

[100] *Supra* note 96.

[101] 45 CFR 86.9(a).

[102] *See* 45 CFR 86.9(a)(1) (requiring a recipient to provide a notice of individuals' rights to applicants for employment and to employees, among other groups of individuals); *id.* 84.8(a) (requiring a recipient to provide a notice of individuals' rights requiring notice to employees, among other groups of individuals).

Although we encourage covered entities to post the notice of individuals' rights in one or more of the most prevalent non-English languages frequently encountered by covered entities in their geographic service areas, we decline to require such posting in the final rule because of the resource burdens and opportunity costs to covered entities. Posted taglines sufficiently alert individuals to the language assistance services available and appropriately balance the educational value of the notices with the burdens to covered entities.

Given that we are not requiring covered entities to post notices in non-English languages, having taglines available in multiple languages is even more important to provide notice to individuals with limited English proficiency of the availability of language assistance services. Thus, we decline to reduce the number of languages in which taglines are required to appear, even for covered entities operating in smaller physical spaces. Covered entities have flexibility in determining the exact size and location of notices and taglines as long as they meet the requirements of this section.

Comment: We received many comments recommending alternative approaches to the proposed rule's requirement for taglines. A few commenters opposed the requirement in proposed § 92.8(d) as unnecessary because oral interpretation is generally available through the customer service telephone line listed on many consumers' health insurance cards. Some commenters suggested that the final rule should permit covered entities to include taglines on the inside of an envelope that a covered entity's health program or activity uses to mail a significant publication or a significant communication. A few commenters suggested replacing tagline text with an icon that would symbolize the availability of oral interpretation services. These commenters suggested that the icon would likely reach more language groups than taglines, and would also occupy substantially less space on significant publications and significant communications.

Response: We decline to eliminate the tagline requirement because such an approach would not provide adequate notice of language assistance services. We appreciate that many health insurance issuers provide telephonic oral interpretation services through their customer service lines/call centers—a number that usually appears on an insured individual's health insurance identification card. We do not, however, regard the mere availability of this information as adequate notice to individuals with limited English proficiency of the availability of language assistance services, much less as notice of each of the components of paragraphs (a)(1)–(7) of § 92.8. Moreover, this approach is not appropriate in all instances because not all covered entities rely on the use of an individual identification card.

In addition, we decline to authorize placement of taglines on the inside of an envelope. Such a placement would diminish the visibility of the taglines, downgrade their importance, and fail to adequately notify individuals because envelopes are generally torn open and then discarded.

With respect to use of an icon, we appreciate the commenters' suggestion and believe that it may hold promise in the future. However, we also decline to require the use of an icon in the final rule. At this point in time, use of an icon alone would not provide consumers with sufficient notice of the availability of language assistance services, which is the intent of § 92.8(d).

Comment: A small number of commenters provided feedback on the application of the requirement to post the notice and taglines in significant publications and significant communications that are small in size, such as brochures, postcards, targeted fliers, small posters, and those that are communicated through social media platforms. Some commenters recommended that the final rule exempt such communications and publications from the posting requirement in § 92.8(f)(1)(i); others recommended that the final rule provide covered entities latitude to substantially shorten the notice and taglines for these publications and communications. Commenters advocating for either of these two positions stated that the limited amount of space in such publications and communications makes them an impractical medium for disclosures of civil rights.

Other commenters opposed any exceptions for significant publications and significant communications that are small-sized, given the importance of notifying individuals about their rights under Section 1557, such as how to obtain auxiliary aids and services for individuals with disabilities and how to obtain language assistance services for individuals with limited English proficiency.

Response: We agree that the notice and tagline requirements for small-sized significant publications and communications should be distinguished from the requirements for significant publications and significant communications that are not small-sized. We also agree with commenters who suggested that small-sized significant publications and significant communications are not well-suited to extensive civil rights disclosures and that they function to drive consumers to other sources of information, such as a covered entity's Web site, where the full civil rights notice and taglines are required by § 92.8(f)(iii). Furthermore, posting the full notice and all 15 taglines to small-sized publications and communications may obscure the content and message of the document, thus undermining the value of such publication or communication. As a result, we are modifying § 92.8(f)(1)(i) to exclude small-sized significant publications and communications from requirements to have a notice and at least 15 taglines.

We disagree, however, with fully exempting significant publications and significant communications that are small-sized from the notice and tagline requirements because these documents, such as tri-fold brochures, pamphlets, and postcards, often serve as a gateway for an individual to apply for, or participate in, a particular health program or activity. To this end, the final rule establishes a separate requirement for small-sized significant publications and significant communications: A covered entity must include a nondiscrimination statement in lieu of the full notice, and taglines in two non-English languages in lieu of all 15 taglines, on small-size significant publications and significant communications.

Specifically, we moved most of the text from proposed paragraph (b) into a new paragraph (b)(1) and added paragraph (b)(2), which addresses the obligation to post a nondiscrimination statement that conveys the information in § 92.8(a)(1) on small-sized significant publications and significant communications. Similarly, we moved most of the text from proposed paragraph (d) into a new paragraph (d)(1) and added paragraph (d)(2), which addresses the obligation to post taglines in at least the top two languages spoken by individuals with limited English proficiency in the relevant State or States on small-size significant publications and significant communications. Finally, we re-designated proposed paragraph (g) as paragraph (h) and we added new paragraphs (g)(1)–(2) to address the posting standards applicable to small-sized significant publications and significant communications.

In choosing a lower threshold than at least the top 15 languages spoken by individuals with limited English proficiency, we chose a concrete number of languages, rather than a threshold formulated as a percentage, because on average about two-thirds of the limited English proficient population in each State[103] is reached by the top two languages spoken by individuals with limited English proficiency in that State. Moreover, requiring a specific number of taglines makes the impact of the requirement predictable for all covered entities in planning how these two taglines, along with the nondiscrimination statement, will fit on their significant communications and significant publications that are small-sized. In almost all States, the top two languages spoken by individuals with limited English proficiency captures Spanish and the other most prevalent non-English language. This approach in paragraphs (b)(2), (d)(2), and (g)(1)–(2) of § 92.8 is more streamlined than requiring the full notice and all 15 taglines but still will inform the majority of individuals with limited English proficiency of their rights to be protected from discrimination under Section 1557 and this part.

In addition, we have added a sample nondiscrimination statement in Appendix A that conveys the information in § 92.8(a)(1), for which the Director will also provide translations. Accordingly, we have modified paragraph (c) of § 92.8 to state that the Director will provide translations of the sample nondiscrimination statement. The translations of the sample notice and sample nondiscrimination statement are for covered entities' discretionary use only—the final rule does not require the posting of the notice or nondiscrimination statement in non-English languages.

Comment: A substantial majority of commenters on § 92.8 provided feedback on the methodology for determining the number of languages in which covered entities will be required to post taglines. Some commenters supported the proposed rule's national methodology because of its simplicity, particularly for covered entities that operate in multiple States. Conversely, other commenters expressed concern that the national standard fails to account for concentrations of particular limited English proficient communities within areas served by covered entities' health programs and activities, including Native American languages spoken by those served in Tribal health programs. One commenter recommended that if the final rule includes a national standard, OCR should require taglines in the top 25 languages spoken nationally by individuals with limited English proficiency. This commenter further recommended that when calculating the top 25 languages, OCR should rely on a data set that "unbundles" bundled language groups, such as "other Asian languages," because some languages represented in bundled categories may be highly prevalent in the service area of a particular covered entity's health program or activity.[104]

Most commenters disfavoring a national methodology recommended that the languages in which covered entities must post taglines should be the top 15 languages spoken State-wide by individuals with limited English proficiency. Commenters explained that the State-wide threshold would be more attuned to the diversity of languages spoken by individuals with limited English proficiency in each State and would align with Federal regulations governing the Marketplaces and qualified health plan issuers.[105] Some of these commenters also recommended that the final rule should require covered entities that serve individuals in multiple States to post more than 15 taglines if the composite list of each State's list aggregates to a total of more than 15 languages. These commenters reasoned that such an interpretation is necessary to further the purpose of addressing the diversity of languages spoken by individuals with limited English proficiency served by a particular covered entity.

Other commenters recommended other approaches, such as requiring taglines in languages in which at least 10% of individuals with limited English proficiency county-wide are exclusively literate,[106] or, in languages spoken by at least 5% of individuals with limited English proficiency or 500 individuals with limited English proficiency in the covered entity's service area, whichever yielded the greater number of languages. Still other commenters recommended that the rule allow covered entities to choose between a State-wide and a national methodology in determining the languages in which to post taglines, depending on the geographic scope of the intended audience for the "significant publication or significant communication" to which the taglines are posted. These commenters explained that a covered entity that operates nationally may choose to post on the covered entity's Web site taglines in languages based on a nationwide threshold but may choose to include on a significant communication to an individual taglines in languages based on a State-wide threshold for the State in which the individual resides.

Response: In response to commenters' recommendations, § 92.8(d)(1) of the final rule requires covered entities to post taglines in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States. Accordingly, paragraphs (d)(1)–(2) of § 92.8 refer to this State-based methodology rather than a national methodology. This threshold captures, on average, 90% of each State's LEP population.

We adopt a State-based approach for three main reasons. First, a State-based methodology is more attuned to the diversity of languages spoken by individuals with limited English proficiency and thus provides notice to more individuals with limited English proficiency.

Second, this State-wide approach better harmonizes with the number of languages in which taglines must be provided by Marketplaces and qualified health plan issuers under 45 CFR

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[103] In estimating this percentage, we used the same data sources, *infra* notes 109 and 110, and the same methodology described in the discussion, *infra*, that we used to identify the languages under the State-based approach in which the Director will translate the sample notice and taglines, as required by § 92.8(c) and (e) of the final rule.

[104] In October 2015, for the second time since the U.S. Census Bureau's American Community Survey (ACS) began, the Census Bureau released detailed tables that unbundle the 39 languages and language groups that ACS publishes annually through its American Factfinder data set. U.S. Dep't of Commerce, U.S. Census Bureau, Data, Detailed Languages Spoken at Home and Ability to Speak English for the Population 5 Years and Over: 2009–2013, *http://www.census.gov/data/tables/2013/demo/2009-2013-lang-tables.html* [hereinafter U.S. Census Bureau, ACS 2009–2013 Detailed Languages] (last visited May 3, 2016). The unbundled data includes 380 possible languages or language groups spoken by individuals who speak English less than "very well." In the proposed rule, HHS explained that it calculated the top 15 languages spoken nationally by individuals with limited English proficiency by relying on the American Factfinder data set that bundles languages. *See* 80 FR 54172, 54179 n.30 (Sept. 8, 2015) (describing the tagline methodology).

[105] 45 CFR 155.205(c)(iii)(A) (beginning no later than November 1, 2016, requiring taglines on Web site content and documents that are critical for obtaining coverage or access to health care services through a qualified health plan for certain individuals in at least the top 15 languages spoken by individuals with limited English proficiency in the relevant State; documents are deemed to be critical for obtaining health insurance coverage or access to health care services through a qualified health plan if they are required to be provided by law or regulation to certain individuals); *see infra* note 107 (describing other tagline requirements applicable to qualified health plan issuers as a result of market-wide regulations).

[106] This 10% county-level threshold for taglines applies to group health plans and health insurance issuers. *See, e.g.*, 45 CFR 147.136(e)(2)(iii), (e)(3) (HHS regulations); 29 CFR 2590.715–2719(e)(2)(iii), (3) (DOL regulations).

155.205(c)(2)(iii)(A).[107] Section 92.8 of this final rule applies to all entities covered by Section 1557, but for Marketplaces and qualified health plan issuers that are subject to the tagline requirements at 45 CFR 155.205(c)(2)(iii)(A) and § 92.8 of this final rule, our State-wide methodology lessens the burden to which Marketplaces and qualified health plan issuers might otherwise be subject.

Third, a county-level approach is impractical because detailed language data are not available for counties with populations of less than 100,000. For counties with populations of at least 100,000 for which detailed language data are available, there are limited data for individuals who speak English less than "very well" and speak a non-English language other than Spanish.[108] For county-level data that are available, moreover, we are concerned that sampling error would render many estimates of small language populations unreliable when assessed within the small geographic area of a county.

With regard to the data used to identify the languages under the State-based methodology in which the Director will translate the sample notice, sample nondiscrimination statement, and taglines, as required by § 92.8(c) and (e) of the final rule, we rely on the most recent bundled and unbundled five-year[109] data available from the U.S. Census Bureau. We rely on the data set that estimates the prevalence of foreign-language speakers who speak English less than "very well,"[110] and we made technical adjustments, such as to remove any spoken languages that do not have a written equivalent in which the Director could translate a tagline.

We intend the threshold's application in § 92.8(d)(1)–(2), which applies to the "relevant State or States," to permit covered entities that serve individuals in more than one State[111] to aggregate the number of individuals with limited English proficiency in those States to determine the top 15 languages required by § 92.8(d)(1), or the top 2 languages required by § 92.8(d)(2) where each respective provision applies.[112] The languages produced from this aggregation are static with respect to the posting requirement in § 92.8(f). Using one of the three posting methods as an example—the posting of the taglines in a covered entity's physical locations required by § 92.8(f)(1)(ii)—a covered entity that operates multiple health programs serving individuals within various States, or that operates a health program with a multi-State service area, complies with § 92.8(f)(1)(ii) when it posts, in its physical locations across the States it serves, taglines in at least the top 15 languages spoken by the aggregate limited English proficient populations of those States, rather than of each individual State. We do not intend to require a covered entity that operates health programs in multiple States (or in States nationwide), or that administers a health program with a multi-State service area (or even a nationwide service area), to tailor the taglines for the specific State in which the entity is physically located or in which an individual with limited English proficiency, with whom the entity communicates, lives. This interpretation best balances the burden on covered entities with the notification of language assistance services to individuals required by § 92.8(d).[113]

We reiterate, however, that the requirements of § 92.8(d)(1)–(2) establish a floor; covered entities are free to include taglines in additional languages beyond 15 languages. For instance, a covered entity that has chosen to aggregate languages may choose to post taglines in all languages on the aggregated list rather than posting just the top 15 languages. Moreover, a covered entity that that operates health programs in multiple States or that administers a health program with a multi-State service area may decide not to aggregate. Instead, the entity may choose to tailor the taglines posted in its physical locations for the specific State in which the physical location exists; similarly, the entity may choose to tailor the taglines on a certain significant communication based on the State in which an individual with limited English proficiency, with whom the entity communicates, lives.

In addition, we note that complying with § 92.8(d)(1)–(2) is not a substitute for complying with the prohibition of national origin discrimination as it affects individuals with limited English proficiency under Section 1557 or this part, including the general nondiscrimination provisions in § 92.101 and the meaningful access provisions in § 92.201 of this final rule. Thus, although this section identifies the languages in which covered entities must post taglines, it does not relieve those entities of the separate obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency who communicate in other languages.

Comment: One commenter recommended including American Sign

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[107] Qualified health plan issuers are also bound by the tagline requirement in market-wide regulations at 45 CFR 147.136(e). Under § 147.136(e), taglines must appear on certain notices and on a health plan or issuer's summary of benefits and coverage, in languages in which 10% of individuals with limited English proficiency county-wide are exclusively literate. *See, e.g.,* 45 CFR 147.136(e)(2)(iii), (e)(3). This methodology applies to a narrower set of documents than those to which the tagline requirement applies in Federal regulations governing Marketplaces and qualified health plan issuers. *Compare* 45 CFR 147.136(e)(2)(iii) (requiring taglines on internal claims and appeals notices) *and* 45 CFR 147.200(a)(5) (requiring taglines on summaries of benefits and coverage) *with* 45 CFR 155.205(c)(2)(iii)(A) (requiring taglines on Web site content and documents that are critical for obtaining health insurance coverage or access to health care services through a qualified health plan). For CMS's most recent technical guidance on the tagline requirement at 45 CFR 155.205(c)(2)(iii)(A), *see* Guidance and Population Data for Exchanges, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR 155.205(c) and 156.250 (Mar. 30, 2016), *https://www.cms.gov/cciio/resources/regulations-and-guidance/index.html#*, Language Access Guide for Exchanges, Qualified Health Plan (QHP) Issuers, and Web-Brokers (last visited May 3, 2016).

[108] U.S. Census Bureau, ACS 2009–2013 Detailed Languages, *supra* note 104 (detailing data parameters in the user notes). At least 25,000 individuals who speak English less than "very well" must speak the same language for the ACS county-level data to identify such language speakers. *Id.*

[109] We rely on the American Community Survey (ACS) 5-year data set because its stability is superior to the 1-year data set, especially when analyzing small populations. U.S. Census Bureau, American Community Survey, When to Use 1-year, 3-year, or 5-year Estimates, *http://www.census.gov/programs-surveys/acs/guidance/estimates.html* (last visited May 3, 2016). The U.S. Census Bureau has discontinued the ACS 3-year data set, which is the data set on which we relied in the proposed rule. U.S. Census Bureau, Census Bureau Statement on the 3-Year American Community Survey Statistical Product (Feb. 2, 2015), *http://content.govdelivery.com/accounts/USCENSUS/bulletins/eeb4af* (last visited May 3, 2016).

[110] U.S. Dep't of Commerce, U.S. Census Bureau, American FactFinder, Language Spoken at Home by Ability to Speak English for the Population 5 Years and Older, ACS Estimates by State: 2010–2014 (released Dec. 2015); U.S. Census Bureau, ACS 2009–2013 Detailed Languages, *supra* note 104. We are not aware of a public data source providing as robust data as the ACS that estimates the languages in which individuals with limited English proficiency read, understand, or speak. Thus, we are relying on a data set identifying individuals who have a limited ability to speak English as a proxy for limited English proficiency population.

[111] This categorization includes covered entities that operate multiple health programs serving individuals within various States or that operate a health program with a multi-State service area.

[112] For a similar approach, *see* HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 FR 10750, 10788 (Feb. 27, 2015) (describing the Department's interpretation of 45 CFR 155.205(c)(2)(iii)(A) and (B) for entities with multi-State service areas).

[113] As newer ACS data become available with respect to the data sets on which we base our methodology, we will determine if and when the at least top 15 languages spoken by individuals with limited English proficiency State-wide change, warranting the Director to make available notices and taglines translated in additional non-English languages.

Language as a language for which a posted tagline be required in § 92.8(d). This commenter stated that taglines denoting the availability of American Sign Language Interpretation could communicate this message by displaying still images, rather than a written language.

Response: We decline to include American Sign Language as a language for which a tagline is required in § 92.8(d)(1)–(2) because the notice of individuals' rights in § 92.8(a)(2), which must be posted in a conspicuously-visible font size and location just like taglines, addresses this issue. Specifically, paragraph (a)(2) requires that the notice of individuals' rights state that the covered entity provides auxiliary aids and services, which include sign language interpreters, to individuals with disabilities when necessary to provide such individuals an equal opportunity to benefit from the entity's health programs or activities.

Comment: A few commenters recommended that the final rule prescribe the location of taglines at or near the beginning of significant publications and significant communications. These commenters provided anecdotal evidence that individuals with limited English proficiency who received multi-page English notices requiring time-sensitive responses failed to see taglines appearing on the last page. Commenters explained that to the individuals' detriment, they discarded the notices without responding, resulting in termination of health insurance coverage and other negative outcomes. A number of commenters recommended that covered entities be required to include the text of all required taglines, not just the in-language link, conspicuously on the homepage of their Web sites.

Response: Although we encourage covered entities to include notices and taglines at the beginning of significant publications and significant communications to ensure that they are meaningfully accessible to the consumer, we decline to require this prescriptive approach as part of the final rule. In some circumstances, such as lengthy publications, it may be necessary to include the notice and taglines at the beginning of a document to meet the requirements of § 92.8(f)(1)(i) and (g)(1)–(2); in others, posting elsewhere, including on a separate insert[114] accompanying the English-language significant publication or significant communication, may be adequate. Furthermore, in today's increasingly electronic and digital age where covered entities may make their first impressions through Web content (often on small mobile devices), we are sensitive to covered entities' need for autonomy in designing and managing the appearance of their public internet home pages.

Although the law requires that individuals receive sufficient notice of language assistance services available to assist individuals with limited English proficiency in understanding the content of a covered entity's Web site, we believe that the use of in-language links permitted under this provision of the proposed rule is the approach that best balances notice to individuals against burden to covered entities.

Comment: Some commenters described the proposed requirement to post the notice in "significant publications and significant communications" as onerous. One commenter recommended that health plans provide the notice to individuals on an annual basis, along with individuals' annual enrollment package, instead of on each "significant publication and significant communication." Some commenters requested that OCR include, in regulation text, the examples of "significant publications and significant communications" we provided in the preamble to the proposed rule, specifically outreach publications and patient handbooks. A few commenters requested that OCR consult with other Federal agencies on the scope of "significant publications and significant communications" to establish a common understanding of this term so that covered entities whose publications and communications are regulated by more than one Federal agency are not subject to conflicting standards.

Other commenters were concerned about OCR's statement in the preamble of the proposed rule that OCR intended the scope of "significant publications and significant communications" to include not only documents meant for the public but also individual letters or notices to an individual, such as a letter to a consumer notifying the individual of a change in benefits. These commenters observed that, pursuant to existing Federal and State law, many letters already include disclosures and other legally mandated information; consequently, the requirement to post both the notice and taglines required in proposed § 92.8(a) and (d), respectively, might dilute the primary message of the letter and confuse or frustrate consumers. Some commenters requested clarification on how "vital documents" as used in the Department's LEP Guidance relates to "significant publications and significant communications" in § 92.8(f)(1)(i) of the proposed rule.

Response: We disagree with commenters' characterization of § 92.8(f)(1)(iii) as "onerous." We acknowledge that compliance with this subsection may impose some limited burdens on covered entities. However, these burdens are outweighed by the benefits that § 92.8(f)(1)(iii) will generate for individuals with limited English proficiency by making them aware, in their own languages, of the availability of language assistance services. Notifying individuals of their rights under Section 1557 and this part, including the availability of language assistance services for individuals with limited English proficiency and the availability of auxiliary aids and services for persons with disabilities, is critical to providing an equal opportunity to access health care and health coverage. For these reasons, OCR intends to interpret "significant communications and significant publications" broadly, which is consistent with the notice provisions of other Federal civil rights authorities, such as Section 504[115] and Title IX.[116]

We decline to limit the posting requirement in § 92.8(f)(iii) to an annual frequency. The notice requirements in other Federal civil rights laws on which we modeled § 92.8 do not contain a similar limitation. Moreover we also note that not every covered entity sends annual notices.

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[114] For instance, Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, and Medicare Prescription Drug Plans must include a "CMS Multi-Language Insert" in the text of certain documents or as a separate page included with certain documents. U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., Medicare Marketing Guidelines, § 30.5.1, 7–8 (Jul. 2, 2015), *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html.*

[115] 45 CFR 84.8(a)–(b) (indicating that methods of notifying individuals' of their rights under Section 504 may include "publication in newspapers and magazines, placement of notices in [Federal financial assistance] recipients' publication[s], and distribution of memoranda or other written communications" as well as "recruitment materials or publications containing general information that . . .[the recipient] makes available to participants, beneficiaries, [and] applicants. . . .").

[116] 45 CFR 86.9(a)(2)(i) (requiring initial notice of individuals' rights to appear in local newspapers, newspapers and magazines published by the recipient of Federal financial assistance, and "memoranda or other written communications distributed to every student . . . of such recipient") and 86.9(b)(1) (requiring each recipient of Federal financial assistance to "prominently include a statement of . . . [the recipient's nondiscrimination policy] in each announcement, bulletin, catalog, or application form which it makes available . . .").

We also decline to enshrine a list of examples of "significant publications and significant communications" in regulation for two main reasons. First, the final rule applies to such a diverse range of covered entities that codifying examples likely would not provide meaningful guidance to the full spectrum of covered entities regulated. Second, we intend to maximize covered entities' flexibility, and each covered entity is in the best position to determine which of its communications and publications with respect to its health programs and activities are significant.

In response to commenters who requested that "significant publications and significant communications" be limited to documents intended for the public, rather than those intended for specific individuals, we decline to limit the intended scope of such documents to those aimed only at the public at-large. We intend the scope of significant publications and significant communications to include not only documents intended for the public, such as outreach, education, and marketing materials, but also written notices requiring a response from an individual and written notices to an individual, such as those pertaining to rights or benefits. We have no reasoned basis to distinguish and exempt significant publications and significant communications intended for specific individuals from significant publications and significant communications intended for the public at-large. Indeed, in some situations, a written notice with information tailored to a specific individual's benefits or participation may be even more important to that individual than a significant publication or significant communication conveying information to the public. Accordingly, an individual's awareness of his or her rights under Section 1557, such as the availability of auxiliary aids and services for persons with disabilities (required in § 92.8(a)(2) to be in the nondiscrimination notice) is just as important as information communicated to the public at-large.[117]

The HHS LEP Guidance uses the term "vital documents" to refer to the documents for which covered entities should prioritize written translations for individuals with limited English proficiency.[118] The HHS LEP Guidance does not define vital documents. Rather, the Guidance states that "[w]hether or not a document (or the information it solicits) is 'vital' may depend upon the importance of the program, information, encounter, or service involved, and the consequence to the LEP person if the information in question is not provided accurately or in a timely manner."[119] The HHS LEP Guidance also provides examples of documents likely to be "vital," such as "consent and complaint forms, . . . [ ] written notices of eligibility criteria, rights, denial, loss, or decreases in benefits or services . . . [ ] [and] [a]pplications to participate in a recipient's program or activity or to receive recipient benefits or services."[120]

OCR intends for "vital documents" to represent a subset of "significant communications and significant publications"" in which covered entities must post the notice (or nondiscrimination statement in § 92.8(b), where applicable) and taglines required by § 92.8(d) and (f), among other electronic and physical locations. In clarifying this point, we emphasize that the HHS LEP Guidance uses the term "vital documents" to address how a covered entity should meet its Title VI obligations to translate entire documents. By contrast, we refer to "significant communications and significant publications" in this rule to identify the documents in which covered entities are required to post the notice of individuals' rights (or nondiscrimination statement, where applicable) and taglines. We are not adopting an across-the-board requirement for covered entities to translate certain written documents into a threshold number of languages.

Comment: Some commenters recommended that OCR provide funding and other resources to non-profit organizations for the purpose of creating a national social media campaign to publicize the requirements of Section 1557.

Response: It is beyond scope of the final rule for OCR to fund organizations' education and outreach efforts. OCR continues, however, to conduct outreach and provide technical assistance to inform covered entities of their obligations and individuals of their rights under Federal civil rights laws, including Section 1557 and this part. OCR will continue to disseminate, via web and social media platforms, fact sheets and other useful materials to covered entities and individuals.

Comment: OCR received a number of comments suggesting revisions to the sample notice in Appendix A and the sample tagline in Appendix B to the proposed rule, such as revisions to improve adherence to plain language writing principles. For example, with respect to the sample notice, a few commenters recommended revisions with respect to the provision of language assistance services: Adding the word "qualified" prior to the word "interpreters," which is listed as a type of language assistance service; replacing "first language" with "primary language"; replacing "translated into other languages" with "written in other languages"; and deleting "when needed to communicate effectively with us."

One commenter objected to the conditional tense of the sample tagline in Appendix B, which stated that "[i]f you speak [insert language], language assistance services may be available to you . . . ," expressing concern that it might deter an individual from asking for or about language assistance services. In addition, commenters suggested that the conditional phrasing of "may be available" is inconsistent with covered entities' obligations under § 92.201 to take reasonable steps to provide meaningful access to each individual with limited English proficiency.

A few commenters recommended that the sample tagline in Appendix B be shortened but offered no specific recommendations on shorter language. Some commenters suggested that OCR consumer test the sample notice in Appendix A of the proposed rule before providing it as a sample in the final rule.

Response: We share commenters' views that the sample notice should clearly convey civil rights information, which can often be complex. We agree with the specific revisions from commenters to improve the sample notice's statement about a covered entity's provision of language assistance services. We have modified Appendix A to the final rule to reflect these revisions, and have made technical revisions to include OCR's contact information for filing a complaint. In our view, the sample notice, with these modifications, adequately apprises individuals of their civil rights under Section 1557 and this part without providing irrelevant or confusing information. We remind covered entities that nothing in the final rule prohibits covered entities from drafting their own notices to meet the requirements of § 92.8(a)(1)–(7), which covered entities are free to consumer test.

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[117] For comparison, the meaningful access requirements of other Federal regulations governing qualified health plan issuers apply to all information that is critical for obtaining health insurance coverage or access to health services through the qualified health plan, including "applications, forms, and notices" and information is deemed to be critical for obtaining health insurance coverage or access to health care services if the issuer is "required by law or regulation" to provide the document to certain individuals. *See* 45 CFR 156.250. CMS's annual guidance to qualified health plan issuers lists examples of documents to which CMS interprets § 156.250 to apply, such as certain correspondence and notifications, summary of benefits and coverage disclosures, formulary drug lists, provider directories, and a plan's explanation of benefits or similar claim processing information. U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., Final 2017 Letter to Issuers in the Federally-facilitated Marketplaces, 80–81 (Feb. 29, 2016), *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf.*

[118] HHS LEP Guidance, *supra* note 49, 68 FR at 47318–19.

[119] *Id.* at 47318.

[120] *Id.* at 47319.

In addition, we have added a nondiscrimination statement to Appendix A that covered entities can post on significant publications and significant communications that are small-sized.

We appreciate commenters' attention to the details of the sample tagline's phrasing. We have modified Appendix B to the final rule to address commenters' concerns that the tagline's conditional wording might deter an individual from asking for or about language assistance services. With technological advancements in language assistance services, we are confident that covered entities have the ability, at a minimum, to obtain qualified oral interpretation services in the languages in which covered entities will provide taglines, consistent with § 92.8(d)(1)–(2); thus, the sample tagline as modified states that language services "are" available. In addition, we replaced the word "contact" with "call" to simplify the vocabulary used for average literacy levels. The modifications we have made amplify taglines' function as a critical gateway to language assistance services. Taglines derive value not only from informing individuals with limited English proficiency of language assistance services but also from prompting individuals to contact the covered entity to obtain language assistance. We decline to shorten the sample tagline because we are concerned that doing so would compromise the tagline's message and intent. We remind covered entities that Appendix B is a sample; covered entities are free to develop their own taglines as long as they provide taglines consistent with § 92.8(d)(1)–(2) of this part.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we have modified § 92.8 and Appendices A and B to part 92 as follows:

In § 92.8(a), we made technical modifications to paragraph (a) and paragraphs (a)(1)–(3). In paragraph (a) we replaced the conjunction "or" with "and." In paragraph (a)(1), we clarified that the nondiscrimination statement of the notice applies to the health programs and activities of a covered entity. In paragraph (a)(2), we inserted the phrase "for individuals with disabilities" after "qualified interpreters" because the final rule now defines qualified interpreters for individuals with disabilities separately from qualified interpreters for individuals with limited English proficiency. In paragraph (a)(3), we added examples of language assistance services to promote alignment with paragraph (a)(2), which provides examples of auxiliary aids and services.

Most of the text in proposed § 92.8(b) is now reflected in new paragraph (b)(1). We added paragraph (b)(2) that requires a covered entity to post a nondiscrimination statement consistent with newly-designated paragraph (g)(1), which applies to significant publications and significant communications that are small-sized. In newly-designated paragraph (b)(1) and (f)(1), we eliminated "English-language" before "notice" to avoid the incongruous result that a significant publication or significant communication written in a non-English language must include a notice written in English.

In § 92.8(c), we added language to convey OCR's plans to translate the sample nondiscrimination statement for covered entities to use at their discretion.

In paragraph (d) of § 92.8, we added paragraph designations (1) and (2) to distinguish the final rule's tagline requirements for significant publications and significant communications that are not small-sized from those that are small-sized. Most of the text in proposed paragraph (d) is now reflected in paragraph (d)(1). In newly-designated (d)(1), we replaced the national threshold with a threshold requiring taglines in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States. In addition, we added a reference to the posting requirement in paragraph (f)(1) of § 92.8 for clarity. Paragraph (d)(2) identifies the tagline requirement for significant publications and significant communications that are small-sized. In paragraphs (c) and (e) of § 92.8, we replaced the national threshold with a reference to the languages triggered by the State-wide methodology described in paragraph (d)(1).

In § 92.8(f), we revised paragraph (f)(1) and paragraphs (f)(1)(i) and (iii). Specifically, in paragraph (f)(1), we made a technical revision to remove an errant reference to paragraph (b) and we replaced the reference to paragraph (d) with (d)(1) to conform to the new paragraph designations of the final rule. In § 92.8(f)(1)(i), we replaced the conjunction "or" with "and" as a technical revision to align the text with the same technical revision in § 92.8(a). In addition, we excluded publications and significant communications that are small-sized from the requirement to post the notice conveying all content in § 92.8(a)(1)–(7) and from the requirement to post all 15 taglines. In paragraph (f)(1)(iii), we clarified the location of the tagline when posted to the covered entity's Web site.

We re-designated paragraph (g) in the proposed rule as paragraph (h) in this final rule. In the final rule, paragraph (g) addresses covered entities' requirements to post a nondiscrimination statement and taglines in significant publications and significant communications that are small-sized. Specifically, paragraph (g)(1) addresses the requirement to post a nondiscrimination statement and paragraph (g)(2) addresses the requirement to post taglines.

Newly re-designated paragraph (h) no longer treats an entity's compliance with particular paragraphs of § 92.8 as constituting compliance with the notice provisions of other Federal civil rights authorities. We revised the paragraph to address a covered entity's permissive authority to combine the content of the notice in paragraphs (a)(1)–(7) of this section with the content of other notices.

In Appendix A to the final rule, we made the following changes to improve the plain language reading of the sample notice and to streamline the sample notice's messaging:

- Deleted "sex stereotypes and gender identity" from the end of the first sentence;
- Replaced "worse" with "differently," and deleted the pronoun "their" prior to listing the bases on which the covered entity does not discriminate;
- Replaced "first language" with "primary language";
- Deleted "when needed to communicate effectively with us";
- Added "qualified" to modify "interpreters" with respect to serving individuals with limited English proficiency;
- Replaced "translated into other languages" with "written in other languages";
- Added placeholders for a covered entity to provide not only the name of its civil rights coordinator but also the individual's title; and

- Added contact information for filing a complaint with OCR.

In addition, we added a sample nondiscrimination statement in Appendix A for covered entities to post in significant publications and significant communications that are small-sized and accordingly broadened the title of Appendix A to reflect its revised scope.

In Appendix B to the final rule, we modified the language by replacing "may be available" with "are available" and by adding language to improve the plain language reading of the sample tagline, by replacing "[c]ontact" with "call."

Subpart B—Nondiscrimination Provisions

Subpart B of the final rule incorporates regulatory provisions implementing the application of the civil rights statutes referenced in Section 1557(a): Title VI, Title IX, the Age Act, and Section 504.

Discrimination Prohibited (§ 92.101)

We proposed that § 92.101 of subpart B prohibit discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity to which Section 1557 or this part applies. We proposed that paragraphs (a) and (b) follow the structure of the implementing regulations for Title VI, Section 504, Title IX, and the Age Act by including a general nondiscrimination provision in paragraph (a) followed by a provision identifying specific discrimination prohibited in paragraph (b). In paragraph (c), we proposed to address exceptions to discrimination prohibited under the Title VI, Section 504, and Age Act regulations. We proposed that paragraph (d) effectuate technical changes in terminology to apply the provisions incorporated from other regulations to the covered entities obligated to comply with this proposed rule.

In paragraph (a)(1) of § 92.101 of the proposed rule, we restated the core objective of Section 1557(a), which prohibits discrimination on the grounds prohibited under Title VI (race, color, or national origin), Title IX (sex), the Age Act (age), or Section 504 (disability) in any health program or activity to which this part applies.

In paragraph (a)(2), we proposed to limit the ways in which the proposed rule applies to employment. We noted that except as provided in § 92.208, which addresses employee health benefit programs, the proposed rule does not generally apply to discrimination by a covered entity against its own employees. Thus, the proposed rule would not extend to hiring, firing, promotions, or terms and conditions of employment outside of those identified in § 92.208; such claims could continue to be brought under other laws, including Title VII, Title IX, Section 504, the ADA and the Age Discrimination in Employment Act,[121] as appropriate. We invited comment on our proposal to exclude these forms of employment discrimination from the scope of the proposed rule.

We proposed that paragraph (b) incorporate into the regulation the specific discriminatory actions prohibited by each civil rights statute which Section 1557 references. We considered harmonizing each of the specific discriminatory actions prohibited across each civil rights law addressed by Section 1557. We noted that although harmonization could reduce redundancy in the specific discriminatory actions incorporated that are similar to one another, harmonization would likely lead to confusion and unintended differences in interpretation that are subtle yet significant. We therefore proposed that paragraphs (b)(1)–(4) incorporate the specific discriminatory actions prohibited under each civil rights law on which Section 1557 is grounded. We sought comment on this proposed approach.

We proposed that paragraph (b)(1) adopt the specific discriminatory actions prohibited by the Title VI implementing regulation, which appear at 45 CFR 80.3(b)(1)–(6).

In paragraph (b)(2)(i), we proposed to address the specific prohibition of discrimination on the basis of disability with which recipients and State-based Marketplaces must comply. In paragraph (b)(2)(i), we proposed to adopt relevant provisions in the Section 504 implementing regulation for federally assisted programs and activities at 45 CFR part 84. We provided that the provisions incorporated are the specific discriminatory actions prohibited at § 84.4(b); the program accessibility provisions at §§ 84.21 through 84.23(b); and the provisions governing education, health, welfare, and social services at §§ 84.31, 84.34, 84.37, 84.38, and 84.41–84.55.

We proposed that paragraph (b)(2)(ii) address the specific prohibitions of discrimination on the basis of disability with which the Department, including the Federally-facilitated Marketplaces, must comply. We proposed that this paragraph adopt relevant provisions in the Section 504 implementing regulation for federally administered programs and activities at 45 CFR part 85. We provided that the provisions adopted are the specific discriminatory actions prohibited at § 85.21(b) and the program accessibility provisions at §§ 85.41 through 85.42 and 84.44 through 84.51.

We proposed that paragraph (b)(3) adopt the specific discriminatory actions prohibited by the Title IX implementing regulation, which appear at 45 CFR 86.3(b)(1) through (8).

We also proposed that paragraph (b)(4) adopt the specific discriminatory actions prohibited by the Age Act implementing regulation, which appear at 45 CFR 91.11(b).

In paragraph (b)(5), we proposed that the specific discriminatory actions prohibited in § 92.101(b)(1) through (4) do not limit the general prohibition of discrimination in § 92.101(a). We noted that this statement is consistent with regulatory provisions in the implementing regulations for Title VI at 45 CFR 80.3(b)(5) and the Age Act at 45 CFR 91.11(c).

In paragraph (c), we proposed to incorporate the exceptions to the general prohibition of discrimination that appear in the implementing regulations for Title VI, Section 504, and the Age Act, as these exceptions have applied to health programs and activities for nearly 40 years. We noted that, generally, the exceptions in the Title VI, Section 504, and Age Act implementing regulations provide that it is not discriminatory to exclude a person from the benefits of a program that Federal law limits to a protected class. We did not address the sex-based distinctions authorized in Title IX and its implementing regulation in the context of education programs or activities. We noted that these distinctions do not necessarily apply in the health care context. However, we also noted that Title IX and the Department of Education's Title IX regulations allow some single-sex education programs when certain requirements are met.[122] We did not propose to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex, but sought comment on what other sex-based distinctions, if any, should be permitted in the context of health programs and activities and the standards for permitting the distinctions.

Finally, we proposed that paragraph (d) effectuate technical changes to apply the provisions incorporated in § 92.101(b) and (c) to covered entities obligated to comply with the proposed rule by, among other things, replacing references to "recipient" in the incorporated provisions with "covered entity."

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[121] 29 U.S.C. 621–634.

[122] 34 CFR 106.34.

The comments and our responses regarding § 92.101 of subpart B are set forth below.

Comment: A few commenters recommended that OCR add the words "or deterred" to the general prohibition of discrimination, so that it would read as follows: "Except as provided in Title I of the ACA, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded or deterred from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which this part applies."

Response: We believe the regulatory text, as it is currently written, conveys the intent to prohibit discriminatory deterrence from participation in a health program or activity. As OCR noted in the preamble to the proposed rule, paragraph (a)(1) of § 92.101 prohibits discrimination on the grounds prohibited under Title VI, Title IX, the Age Act, and Section 504 in any health program or activity to which this part applies. It is well established under these and other civil rights law that deterrence on the basis of a prohibited criterion is a form of discrimination. Similarly, discrimination on the basis of perceived race, color, national origin, sex, age, or disability is prohibited discrimination under the final rule, as it is under the authorities referenced in Section 1557.

Comment: One commenter asked for clarification that, when scientific evidence supports differential treatment to ensure safe, high-quality care, such treatment would not be considered discriminatory. This commenter pointed out that the risks and benefits of treatments may differ due to characteristics such as age, gender, physical stature, and genetics. For example, based on the best available science, experts have judged that, for men and younger women, absent a known family history, the risks associated with radiation exposure from routine mammograms outweigh the benefits. Thus, practice guidelines suggest not administering screening mammograms to women under a certain age or to men.

Response: Scientific or medical reasons can justify distinctions based on the grounds enumerated in Section 1557. We affirm this understanding of the final rule and believe that the regulatory text encompasses that approach.

Comment: A few commenters asked that OCR prohibit discrimination in health programs or activities on the basis of "health status, claims experience, medical history, or genetic information" in addition to race, color, national origin, sex, age, and disability.

Response: This rule implements Section 1557 of the ACA, which prohibits discrimination on the bases of race, color, national origin, sex, age, and disability. Accordingly, the commenters' request is beyond the scope of this rule. However, OCR recognizes that discrimination based on health status, claims experience, medical history, or genetic information can, depending on the facts, have a disparate impact that results in discrimination on a basis prohibited by Section 1557 and will process complaints alleging such discrimination accordingly. In addition, such discrimination also may violate other laws, such as other provisions of the ACA or the Genetic Information Nondiscrimination Act of 2008.[123]

Comment: Many commenters disagreed with the approach taken in the proposed rule to exclude discrimination in employment in areas other than employee health benefits. Commenters stated that the text of Section 1557 does not exclude employment discrimination; that Section 1557 protects "individuals," similar to Title IX's protection of "person[s];" and that Title IX has been interpreted to protect not just students but employees of educational institutions. They also noted that Section 504 covers employment without exception and that Title VI covers employment discrimination when it affects beneficiaries of the covered program.[124]

Response: For the reasons stated in the preamble to the proposed rule, OCR declines to interpret Section 1557 to grant itself jurisdiction (outside the context of employee health benefit plans under circumstances set out in § 92.208) over claims of employment discrimination brought by employees against their employers that are covered entities. In holding that both Title IX and Section 504 broadly prohibit discrimination in employment, the Supreme Court relied heavily on the legislative history and underlying purpose of these statutes.[125] By contrast, there is no indication that broadly prohibiting employment discrimination was a chief purpose of Section 1557, which is focused on discrimination against participants in health programs and activities. To the extent that employees who are subject to discrimination are employed by entities that are covered under other employment discrimination laws, their complaints can be brought under those other laws. And as to employees of small employers, we do not believe that Congress in Section 1557 intended to alter, across the board, the longstanding exclusion of small employers from most employment discrimination laws. That said, nothing in this rule is intended to alter the established principles underlying the unlimited coverage of employment discrimination under both Title IX and Section 504, and OCR will process such claims brought under these statutes under its longstanding procedures.[126]

Comment: Some commenters asked that OCR clarify that Section 1557's prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability includes intersectional discrimination that might affect persons who are part of multiple protected classes. For example, discrimination against an African-American woman could be discrimination on the basis of both race and sex.

Response: OCR is clarifying here that Section 1557's prohibition of discrimination reaches intersectional discrimination. We believe that the regulatory text encompasses this approach.

Comment: Commenters noted that various forms of harassment in health care can discourage individuals from seeking care and suggested that OCR include a separate provision that explicitly prohibits all forms of harassment based on protected characteristics, including sexual harassment and other forms of sex-based harassment.

Response: OCR recognizes that various forms of harassment can impede an individual's ability to participate in or benefit from a health program or activity and can thus constitute unlawful discrimination under Section 1557 and this part. Under Title IX, harassing conduct creates a hostile environment if the conduct is sufficiently serious to interfere with or limit an individual's ability to participate in or benefit from a program.[127] For example, a provider's persistent and intentional refusal to use a transgender individual's preferred name and pronoun and insistence on using those corresponding to the individual's sex assigned at birth constitutes illegal sex discrimination if such conduct is sufficiently serious to create a hostile environment. Similarly, a provider using derogatory language because an individual is an unmarried sexually active or pregnant woman constitutes illegal sex-based harassment if such conduct is sufficiently serious to create a hostile environment. Consistent with the well-established interpretation of existing civil rights laws, OCR interprets the final rule to prohibit all forms of unlawful harassment based on a protected characteristic. Because it has been long-established that harassment is a form of prohibited discrimination under each of the laws cited in Section 1557 and this part, OCR does not believe a separate harassment provision is necessary and therefore declines to revise the proposed rule to include one.

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[123] *Supra* note 3.

[124] *See North Haven Bd. of Educ.* v. *Bell*, 456 U.S. 512 (1982).

[125] *Id.* at 522–30; *Consolidated Rail* v. *Darrone*, 465 U.S. 624, 626 (1984).

[126] Moreover, nothing in this rule is intended to affect OCR's ability to address discrimination against patients on a prohibited basis, even where that discrimination is effectuated through actions against a covered entity's employee. If, for example, a medical practice that receives Federal financial assistance fired a Hispanic doctor because the practice no longer wished to serve the doctor's predominantly Hispanic, limited English proficient patients, OCR could pursue relief on behalf of affected patients to ensure that their access to the practice was not discriminatorily denied. *Cf.* 45 CFR 80.3(c)(3) (Title VI applies where discrimination in employment tends to exclude individuals, on the basis of race, color, or national origin, from participation in a covered program).

Comment: Many commenters recommended that OCR add regulation text stating that the Tri-Agency Guidance[128] imposes legally enforceable obligations on entities covered by Section 1557 and that OCR has direct authority to enforce the Tri-Agency Guidance as well as the statutory and regulatory provisions therein articulated.[129] The Tri-Agency Guidance describes how States can structure their application and enrollment processes in compliance with Title VI and program authorities to ensure that State agencies do not administer federally assisted public benefit programs in a manner that delays or denies services to eligible individuals, including children, living in mixed-immigration status households.

Commenters asked for such regulatory language based on concerns that some covered entities administer their programs in a manner that discriminates based on national origin by delaying or denying access to public benefits based on practices such as: Erecting onerous documentation requirements; denying eligible applicants the opportunity to prove eligible income, identity, citizenship status, or immigration status; or making generalized assumptions about applicants' eligibility based on the actual or perceived immigration status or national origin of any family member.[130] Commenters also expressed concern that some covered entities fail to understand the eligibility differences between various immigrant visa statuses and length of residency requirements, fail to distinguish between applicants and non-applicants in requests for Social Security numbers (SSNs), or require the disclosure of SSNs or immigration status without first explaining the use or confidentiality of this information.

Response: OCR appreciates hearing from commenters on this important issue. However, we decline to explicitly reference, in regulation, the Tri-Agency Guidance and the authorities therein articulated for two main reasons. First, it is beyond the scope of this final rule to address program authorities over which OCR does not have enforcement authority.

Second, regulatory modifications to the proposed rule are unnecessary to allow OCR to address a covered entity's policy or practice, such as requiring the disclosure of SSNs or certain citizenship or immigration status information, that raises compliance concerns under Section 1557's prohibition of national origin discrimination. OCR addresses such issues under Title VI.[131] We similarly have authority to address such issues under Section 1557 and this part when, for example, an individual's complaint alleges that a covered entity has implemented a facially-neutral policy, such as requiring the disclosure of immigration status from applicants and non-applicants, that has a disparate impact on individuals of a particular national origin group.

Thus, to the extent that the Tri-Agency Guidance identifies situations that may raise Title VI compliance concerns and offers best practices for resolving those concerns, this information is equally applicable to health programs and activities covered under Section 1557 as it is to the health and human service programs addressed in the Tri-Agency Guidance. The Department continues to adhere to the principles set forth in the Tri-Agency Guidance in the implementation of the Department's programs[132] and through OCR's enforcement of Title VI. OCR intends to apply these principles in our enforcement of Section 1557 and this part and will continue to accept complaints alleging that covered entities' actions deter eligible individuals from applying for benefits offered by health programs and activities on the basis of their national origin. Section 1557 and this part, however, do not alter programmatic laws and regulations that restrict eligibility for particular health programs to persons of certain immigration or citizenship statuses, and thus allow covered entities to make requests for that information when required by such authorities.[133]

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[127] *See, e.g.*, U.S. Dep't of Educ., Office for Civil Rights, Questions and Answers on Title IX and Sexual Violence (2014) at A–2, available at *http://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf.*

[128] U.S. Dep't of Health & Human Servs. and U.S. Dep't of Agriculture, Policy Guidance Regarding Inquiries into Citizenship, Immigration Status and Social Security Numbers in State Applications for Medicaid, State Children's Health Insurance Program (SCHIP), Temporary Assistance for Needy Families (TANF), and Food Stamp Benefits (2000) [hereinafter Tri-Agency Guidance], *http://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/tri-agency/index.html* (describing how States can structure their facially-neutral policies and practices to enroll eligible children and families of all national origins to reduce and eliminate access barriers).

[129] In addition to Title VI, the Tri-Agency Guidance addresses the Privacy Act of 1974 and program authorities authorizing and implementing Medicaid, CHIP, Temporary Assistance for Needy Families, and the Food Stamp Program. *Id.* at 1–2, Q2.

[130] The Tri-Agency Guidance addresses the circumstances under which a State may not deny benefits when a non-applicant applying on behalf of a child, or a non-applicant household member, does not provide information regarding his or her citizenship status, immigration status or a Social Security number. The Guidance recommends that public benefits applications allow non-applicants to declare early in the process whether they are seeking benefits only on behalf of an eligible child or family member so that further inquiry is limited to factors necessary for determining the child's or family member's eligibility. *Id.* at 206, Q3–Q7.

[131] *See* HHS OCR VRA with AZ Agencies, *supra* note 53, (resolving cognizable complaints of national origin discrimination under Title VI following implementation of an Arizona State law requiring State employees, in the administration of public benefits programs, to report "discovered violations of federal immigration law" to U.S. Immigrations and Customs Enforcement).

[132] *See, e.g.*, 77 FR 18310, 18355 (Mar. 27, 2012) (applying the principles of the Tri-Agency Guidance to Marketplace^{SM} regulations on the health insurance application process); U.S. Dep't of Health & Human Servs., Office of Community Servs., Admin. on Children & Families, HHS Guidance on the Use of Social Security Numbers and Citizenship Status Verification for Assistance by LIHEAP Grantees' Programs, A6 (2014), *http://www.acf.hhs.gov/programs/ocs/resource/liheap-im-hhs-guidance-on-the-use-of-social-security-numbers-ssns-and-citizenship-status-verification* (strongly encouraging LIHEAP Grantees to structure their eligibility processes to avoid the delay or denial of benefits to eligible persons in mixed-immigration status households); U.S. Dep't of Health & Human Servs., Admin. on Children & Families, Office of Child Care, Clarifying Policy Regarding Limits On The Use Of Social Security Numbers Under the Child Care and Development Fund and the Privacy Act Of 1974, Program Instr. No. ACYF–PI–CC–00–04 (2000), *http://www.acf.hhs.gov/programs/occ/law/guidance/current/pi0004/pi0004.htm* (requiring States to make clear that the provision of a SSN is voluntary and child care benefits will not be denied or withheld for failure to provide a SSN).

Comment: A few commenters recommended that HHS clarify its longstanding position that the regulations implementing Section 504 require health care entities with fewer than 15 employees to provide auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question. These commenters pointed out that while 45 CFR 84.52(d)(1) requires the provision of auxiliary aids only by covered entities with 15 or more employees, 45 CFR 84.52(d)(2) provides that the Director may require recipients with fewer than 15 employees to provide auxiliary aids where the provision of aids would not significantly impair the ability of the recipient to provide its benefits or services. The commenters recognized that in 2000, HHS issued a notice in the **Federal Register** announcing that the Director had decided to require recipients with fewer than 15 employees to provide appropriate auxiliary aids pursuant to 42 CFR 84.52(d)(2).[134] However, the commenters also asserted that some judicial decisions have questioned whether the Director's notice constitutes a binding legislative rule or merely a policy statement by HHS.[135] Accordingly, these commenters were concerned that the proposed rule's incorporation of 45 CFR 84.52(d) might not be clear enough to also incorporate the Director's notice that health care entities with fewer than 15 employees must provide auxiliary aids and services on the same basis as health care entities with 15 or more employees.

Response: To ensure clarity as to our intent, we have revised the language in § 92.101(b)(2)(i) to delete the reference to 45 CFR 84.52(d) and have added new language to that section requiring covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills where necessary to afford such persons an equal opportunity to benefit from the service in question.

As explained in the Director's original notice adopting this policy, OCR believes that Section 504's auxiliary aids and services requirement should be applied to covered entities with fewer than 15 employees in the interest of uniformity and consistent administration of law. Under Title III of the ADA, privately operated public accommodations are obligated to provide appropriate auxiliary aids and services, regardless of their size, where necessary to ensure effective communication with individuals with disabilities, unless they can demonstrate that taking such steps would fundamentally alter the nature of their program, services or activities, or would result in undue financial and administrative burdens.[136] OCR's decision to require all entities, regardless of size, to provide auxiliary aids and services under Section 1557 and this part thus furthers consistency among disability discrimination laws; importantly, it also furthers the ACA's goal of improving access to health coverage and health care because requiring all entities to provide auxiliary aids and services will result in enhanced services for people with disabilities. Moreover, because this requirement has been OCR's policy for more than a decade, covered entities are familiar with the obligations it imposes.

Comment: A few commenters asked that OCR add language to the rule declaring that medical treatment for individuals with disabilities must be as effective as treatment for individuals without disabilities.

Response: At § 92.101(b)(2)(i), the final rule incorporates 45 CFR 84.4(b)(1)(iii) of the Section 504 implementing regulation, which states that recipients may not provide qualified individuals with disabilities "with an aid, benefit, or service that is not as effective as that provided to others. . . ." Such benefits include medical treatment, though recipients cannot, and are not required under the rule to, ensure equally effective outcomes.

Comment: A number of commenters urged that OCR make clear that, consistent with the requirements of Title II of the ADA and Section 504,[137] disability-based discrimination under Section 1557 encompasses the needless segregation of individuals with disabilities. They pointed, in particular, to the need to make clear that covered entities must make coverage and reimbursement decisions that support serving individuals with disabilities in integrated settings unless doing so would fundamentally alter the entities' service systems, citing to the HHS Guidance on Medicaid Managed Care.[138]

Response: We agree that since Section 1557 explicitly incorporates Section 504's prohibitions against disability-based discrimination, it therefore encompasses a ban on the unnecessary segregation of individuals with disabilities. As such, and as required by Title II of the ADA and Section 504 and interpreted in *Olmstead* v. *L.C.*[139] and its progeny, public entities (State and local governments) must administer services to individuals with disabilities in the most integrated setting appropriate to their needs unless doing so is a fundamental alteration of the public entity's service delivery system. The "most integrated setting" mandate applies to the full spectrum of the public entity's service delivery system, including coverage and reimbursement decisions, when the entity "(1) directly or indirectly operates facilities and or/ programs that segregate individuals with disabilities; (2) finances the segregation of individuals with disabilities in private facilities; and/or (3) through its planning, service system design, funding choices, or service implementation practices, promotes or relies upon the segregation of individuals with disabilities in private facilities or programs." [140] OCR will continue its ongoing *Olmstead* enforcement efforts under Section 504 and Title II of the ADA, as well as Section 1557 and this part, where appropriate.

Comment: Several commenters recommended that OCR specify that age-related distinctions are prohibited, apart from exclusions in the Age Act for (1) age distinctions contained in a

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[133] *See, e.g.*, 45 CFR 155.305(f)(6) (in some cases, a Marketplace^{SM} must require the SSN of an individual who is not requesting coverage for himself or herself, but whose SSN could be used to verify eligibility information for a household member who is requesting Marketplace^{SM} coverage and financial assistance, such as a child).

[134] *See* U.S. Dep't of Health & Human Servs., Office for Civil Rights; Section 504 of the Rehabilitation Act of 1973; Notice of Exercise of Authority Under 45 CFR 84.52(d)(2) Regarding Recipients With Fewer Than Fifteen Employees, 65 FR 79368 (Dec. 19, 2000).

[135] *See, e.g., Columbia* v. *Gregory*, Civ. No. 08–cv–98, 2008 WL 4192437, *4 (D.N.H. Sep. 9, 2008).

[136] *See* 42 U.S.C. 12182(b)(2)(A)(iii).

[137] *See* 28 CFR 35.130(b)(7) (requiring public entities to administer services to individuals with disabilities in the most integrated setting appropriate to their needs); 45 CFR 84.4(b)(2); *Olmstead* v. *L.C.*, 527 U.S. 581 (1999).

[138] U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Services, Guidance to States Using 1115 Demonstrations or 1915(b) Waivers for Managed Long Term Services and Supports Programs 3 (May 20, 2013), *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/downloads/1115-and-1915b-mltss-guidance.pdf.*

[139] *527 U.S. 581 (1999).*

[140] U.S. Dep't of Justice, Statement of the Department of Justice on Enforcement of the Integration Mandate of Title II of the Americans with Disabilities Act and *Olmstead* v. *L.C.*, (June 21, 2011), *http://www.ada.gov/olmstead/q&a_olmstead.htm.*

Federal, State or local statute or ordinance that provide benefits based on age, establish criteria for participation in age-related terms, or describe intended beneficiaries to target groups in age-related terms, and (2) actions that reasonably take into account age as a factor necessary to the normal operation or the achievement of any statutory objective of such program or activity. Under these comments, for example, a decision to limit coverage of a service to individuals in a particular age range, even though that service is also effective for individuals of other ages, would violate Section 1557 if the age limitation is not based on a statute or ordinance and is not necessary for the normal operation or achievement of the goals of the service.

Response: OCR declines to adopt the standard recommended by the commenters. As noted elsewhere, the rule permits actions based on age to overcome the effects of conditions that resulted in limited participation in the covered entity's health program or activity based on age.[141] We also note that other provisions of the rule incorporate provisions in the regulation implementing the Age Act that permit age distinctions in HHS regulations and a recipient's provision of special benefits to the elderly or children.[142]

Comment: A few commenters asked that OCR clarify that State mandates that have age limits are exempt and that States are allowed to create new State mandates that have age distinctions if that is clinically appropriate.

Response: As reflected in the provision of the final rule at § 92.2(b)(1), age distinctions contained in Federal, State, or local statutes or ordinances adopted by an elected, general purpose legislative body are not covered by the final rule. States may adopt new laws that contain age distinctions; those distinctions would not violate the final rule.[143]

Comment: One commenter asked us to clarify the application of Section 1557 with respect to age rating in health insurance plans and related employer contributions.

Response: As we noted above, OCR is incorporating in the final rule the exclusions found in the Age Act, such that the provisions of the proposed rule would not apply to any age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which provides any benefits or assistance to persons based on age, establishes criteria for participation in age-related terms, or describes intended beneficiaries to target groups in age-related terms.[144] For instance, age rating in premium rates within a 3:1 ratio in Marketplace^{SM} plans would not violate Section 1557 because it is permitted under the ACA.[145] Further, this rule would not prohibit a covered entity from establishing and applying, or offering a plan on a Marketplace^{SM} that establishes or applies, in a nondiscriminatory manner, neutral rules related to employer contribution amounts, such as contributing a fixed percentage or dollar amount of each employee's premium or placing a cap on the total amount of employer contributions, even though the dollar amount of the contribution or the employee's share of the premium may be smaller or greater for some employees than for others based on the permissible age rating of the employee's premium.

Comment: One commenter recommended that OCR clarify that in order to operate in a nondiscriminatory manner, issuers must ensure that their plans do not impose arbitrary age, visit, or coverage limits. This commenter pointed out that children often need more frequent preventive and supportive services than adults, including immunizations, developmental assessments and screenings, and nutritional counseling, to enable them to maintain or improve their health into adulthood. Furthermore, children with special health needs may need additional services, such as speech or physical therapy, on a more frequent basis than adults to enable them to develop specific skills or meet their developmental potential. Similarly, children will also require replacement of durable medical equipment or devices on a much more frequent schedule than is provided in an adult benefit package.

Response: OCR agrees that arbitrary age, visit, or coverage limitations could constitute discrimination, including discrimination based on age, in certain cases, for example where consideration of age is not necessary to the normal operation of a health program. In addition, as noted above, where differential treatment is justified by scientific or medical evidence, such treatment will not be considered discriminatory. The general prohibition of discrimination in the rule applies to these issues.

Comment: Commenters noted that due to the educational context for which they were created, Title IX regulations do not reach the full breadth of discriminatory actions on the basis of sex that are prohibited by Section 1557; these commenters recommended that the final regulation incorporate prohibitions from Title VI, Section 504, and the Age Act to more fully address discrimination on the basis of sex in health programs and activities. In addition, commenters stated that the final rule should make clear that in the absence of a finding of discrimination, a covered entity may take affirmative action to overcome the effects of conditions which resulted in limited participation by persons on the basis of sex.

Response: OCR appreciates the concern raised by the commenters that, due to the fact that Title IX applies only to educational programs, the full range of specific discriminatory actions prohibited under other laws is not explicitly included in Title IX's regulations. OCR has revised the final regulation to incorporate additional language in § 92.101(b)(3) to help clarify the full breadth of discriminatory actions that can constitute sex discrimination under Section 1557. Additionally, both the proposed and the final rule make clear in § 92.6 (Remedial Action and Voluntary Action) that covered entities are permitted, but not required, to take voluntary action in the absence of a finding of discrimination to overcome the effects of conditions that result or resulted in limited participation by persons based on any prohibited ground covered under the regulation.

Comment: Several commenters noted that although sex-specific programs may be clinically necessary in some instances, for example, in clinical trials that aim to determine whether sex differences exist in the manifestation or recommended treatment of certain diseases, the Department should clarify that sex-specific programs—*i.e.*, those in which participation is limited to members of one sex only—are permissible only when they are narrowly tailored and necessary to accomplish an essential health purpose.

Response: OCR agrees with commenters that sex-specific programs (programs limited exclusively to one sex) should be permitted only under limited circumstances. OCR believes that the constitutional standard established by the Supreme Court in

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[141] *See* § 92.101(c).

[142] *See* § 92.101(c) (incorporating 45 CFR 91.17).

[143] We note that age limits may violate CMS regulations under the ACA and covered entities are responsible for ensuring compliance with all applicable CMS regulations and other Federal laws.

[144] *See* 42 U.S.C. 6103(b).

[145] 42 U.S.C. 300gg(a)(1)(A)(iii). *See also* 45 CFR 147.102.

United States v. *Virginia*[146] provides the most appropriate level of protection and thus has chosen to adapt this standard for application in evaluating the lawfulness of sex-specific health programs or activities under Section 1557 and this part. In *Virginia*, the Court stated that a governmental entity attempting to justify a sex-specific program must demonstrate an "exceedingly persuasive justification" for a sex-based classification in accordance with the U.S. Constitution's Equal Protection Clause.[147] As the Court explained, this means that the governmental entity must show "at least that the [challenged] classification serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives."[148] In *Virginia*, which challenged Virginia Military Institute's male-only admissions policy, the Court found that the governmental entity had fallen "far short of establishing the exceedingly persuasive justification" necessary to sustain a sex-based classification.[149] The Court made clear that proffered justifications cannot rely on overbroad generalizations and cannot be hypothesized or invented post hoc in response to litigation.[150]

Under this demanding standard, as adapted in this rule, a sex-specific health program or activity classification is unlawful unless the covered entity can show an exceedingly persuasive justification for it, that is, that the sex-based classification is substantially related to the achievement of an important health-related or scientific objective. In evaluating a complaint of discrimination challenging a covered entity's sex-specific health program or activity, OCR may consider a variety of factors relevant to the particular program or activity. In all cases, however, OCR will expect a covered entity to supply objective evidence, and empirical data if available, to justify the need to restrict participation in the program to only one sex. In no case will OCR accept a justification that relies on overly broad generalizations about the sexes.

Under this standard, OCR anticipates that most health researchers will be able to justify sex-specific clinical trials, such as those that test treatments for sex-specific conditions or that evaluate differences in responses to treatment regimens among the sexes, based upon the scientific purposes of the study. Where there is no clinical or scientific rationale for making a program sex-specific, by contrast, a covered entity that offers such a program would need to demonstrate, through such means as research literature, empirical data, accepted professional standards, and/or facts specific to participants in the program, that maintaining the sex segregation of the program is necessary for the program to achieve its purpose. Overly broad generalizations would not be sufficient.

No commenters asked OCR to adopt the sex-specific standards authorized in Title IX or the Department of Education's Title IX regulations. OCR has chosen to apply an adapted constitutional standard under Section 1557 rather than the standard authorized in Title IX and the Department of Education's Title IX regulations because, as noted in the proposed rule, and by several commenters, the single-sex educational exceptions found in Title IX and the Department of Education's Title IX regulations—such as exceptions for some single-sex education programs (*e.g.*, contact sports in physical education classes; classes on human sexuality; and choruses) when certain requirements are met—do not readily apply in a context grounded in health care.

In addition, we note that OCR's adaptation of the constitutional standard as the standard to be applied to sex-specific health programs or activities under Section 1557 is consistent with the constitutional standard that already applies to sex-specific public health programs and activities, which are covered entities under this rule if they receive Federal financial assistance. OCR has adapted the standard to use the term "important health-related or scientific objective," in recognition of the fact that the rule's provision on sex-specific programs or activities applies to both private and public covered entities in the context of health programs and activities. The same Section 1557 nondiscrimination standards, including this adapted standard, apply to health programs or activities subject to this rule whether public or private covered entities operate them.

Finally, as we initially noted in the proposed rule, we do not intend to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex. OCR recognizes that under some existing Federal, State and local laws, rules or regulations, certain types of sex-specific facilities such as restrooms may be permitted. The approach taken by OCR is consistent with the long standing approach taken to these types of facilities.

However as previously stated in the discussion of the definition of "on the basis of sex" in § 92.4, even where it is permissible to make sex-based distinctions, individuals may not be excluded from health programs and activities for which they are otherwise eligible based on their gender identity.[151] Courts have rejected claims that any legal right to privacy is violated and that one person suffers any cognizable harm simply by permitting another person access to a sex-specific program or facility which corresponds to their gender identity.[152]

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.101 with the following modifications:

We have re-designated § 92.101(b)(1) as § 92.101(b)(1)(i), and added a new section § 92.101(b)(1)(ii), which prohibits aiding or perpetuating discrimination against an individual by providing significant assistance to an entity or person that discriminates on the basis of race, color, or national origin against beneficiaries of the covered entity's health program or activity. Similarly, we have re-designated § 92.101(b)(4) as § 92.101(b)(4)(i), and added a new section § 92.101(b)(4)(ii), which prohibits aiding or perpetuating discrimination against an individual by providing significant assistance to an entity or person that discriminates on the basis of age against health program or activity beneficiaries. These provisions complement similar provisions incorporated in the final rule with respect to disability and sex discrimination and are included to ensure that we are providing the same protections from race, color, national origin, and age discrimination as are provided with respect to sex and disability discrimination.

In addition, we have changed the language in § 92.101(b)(2)(i) to exclude reference to 45 CFR 84.52(d). We are re-designating the existing regulation text at § 92.202 as § 92.202(a), and adding a new subsection, § 92.202(b) that requires covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

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[146] 518 U.S. 515 (1996).

[147] *Id.* at 531–32.

[148] *Id.* at 532–33 (internal citations omitted).

[149] *Id.* at 533–34.

[150] *Id.* at 533.

[151] *See Lusardi* v. *McHugh*, U.S. Equal Employment Opportunity Comm'n Appeal No. 0120133395, Agency No. ARREDSTON11SEP05574, 2015 WL 1607756 (April 1, 2015) (finding Agency's denial of Complainant's access to the common women's restroom on account of her gender identity violated Title VII), *http://www.eeoc.gov/decisions/0120133395.txt*.

[152] *See, e.g., Crosby*, 763 F. Supp. 666; *cf Cruzan*, 294 F.3d 981.

We have re-designated the existing regulation text at § 92.101(b)(3) as § 92.101(b)(3)(i). We have added new subsections, § 92.101(b)(3)(ii) and § 92.101(b)(3)(iii) to clarify the full breadth of discriminatory actions prohibited by Section 1557 on the basis of sex. Last, we have added a new subsection, § 92.101(b)(3)(iv) to clarify when covered entities may provide a sex-specific health program or activity.

Subpart C—Specific Applications to Health Programs and Activities

Section 1557 is unique among Federal civil rights laws in that it specifically addresses discrimination in health programs and activities. To provide additional specificity regarding nondiscrimination requirements in this setting, Subpart C builds upon pre-existing civil rights regulations referenced in Subpart B.

Meaningful Access for Individuals With Limited English Proficiency (§ 92.201)

Overview of § 92.201

In § 92.201, OCR proposed to effectuate Section 1557's prohibition on national origin discrimination as it affects individuals with limited English proficiency in health programs and activities of covered entities.

We explained that for individuals with limited English proficiency, lack of proficiency in English—and the use of non-English languages—is a direct outgrowth of, and is integrally tied to, their national origins.[153] It is well-established under Title VI and its implementing regulation that a prohibition on national origin discrimination requires covered entities to take reasonable steps to provide meaningful access to individuals with limited English proficiency.[154] The U.S. Supreme Court has held that the provision of language assistance services is essential to ensure the equality of opportunity promised by nondiscrimination laws.[155] As we stated in the Department's 2000 LEP Policy Guidance:

> The key to providing meaningful access for LEP persons is to ensure that the recipient/covered entity and LEP person can communicate effectively. The steps taken by a covered entity must ensure that the LEP person is given adequate information, is able to understand the services and benefits available, and is able to receive those for which he or she is eligible. The covered entity must also ensure that the LEP person can effectively communicate the relevant circumstances of his or her situation to the service provider.[156]

General Requirements § 92.201(a), (b) and (c)

In § 92.201(a), we proposed to adopt the well-established principle that covered entities must take reasonable steps to provide meaningful access to health programs and activities for all individuals with limited English proficiency whom the covered entities serve or encounter.[157] We provided that, consistent with our longstanding enforcement of Title VI, we intended the general obligation in paragraph (a) to be a context-specific standard that the Director considers in light of the particular facts.[158]

We stated that the proposed standard balances two core principles critical in effectuating Section 1557's prohibition of national origin discrimination. First, the Department must "ensure that [health programs and activities] aimed at the American public do not leave some behind simply because they face challenges communicating in English." [159] We noted that provider-patient communication is essential to the concept of patient centeredness, which is a core component of quality health care and has been shown to improve patients' health and health care.[160] Second, we stated that the level, type and manner of language assistance services required under paragraph (a) should be assessed based on the relevant facts, which may include the operations and capacity of the covered entity.

For these reasons, proposed paragraph (b) identified how the Director will evaluate whether a covered entity has met the requirement in paragraph (a).[161] In paragraph (b)(1), we proposed to require the Director to consider, and give substantial weight to, the nature and importance of the health program or activity, including the particular communication at issue. In paragraph (b)(2), we proposed to require the Director to take other relevant factors into account and identified some of those that might be relevant.

In paragraphs (b)(2)(i) and (ii), OCR proposed to identify the length, complexity, and context of the communication as potentially relevant factors in a particular case. We noted that where a communication is particularly long or complex, a covered entity might be required to provide a means for an individual with limited English proficiency to be able to refer back to the information communicated by providing, for instance, a document written in the individual's primary language or an audio file of the information conveyed orally.

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[153] *See, e.g.*, 80 FR at 54182.

[154] *See, e.g.*, *Lau* v. *Nichols*, 414 U.S. 563, 566 (1974) (interpreting Title VI and its implementing regulations to require a school district with students with limited English proficiency of Chinese origin to take affirmative steps to provide the students with a meaningful opportunity to participate in Federally funded educational programs); HHS LEP Guidance, *supra* note 49, 68 FR at 47313 ("[T]he failure of a recipient of [F]ederal financial assistance from HHS to take reasonable steps to provide LEP persons with [a] meaningful opportunity to participate in HHS funded programs may constitute a violation of Title VI and HHS's implementing regulations"); U.S. Dep't of Health & Human Servs., Office for Civil Rights, Policy Guidance, Title VI Prohibition against National Origin Discrimination As It Affects Persons with Limited English Proficiency, 65 FR 52762, 52765 (August 30, 2000) ("The most important step in meeting this [meaningful access] obligation is for recipients of Federal financial assistance such as a grants, contracts, and subcontracts to provide the language assistance necessary to ensure such access, at no cost to the LEP person."). *See also* Exec. Order No. 13166, *Improving Access to Services for Persons with Limited English Proficiency*, 65 FR 50121 (Aug. 11, 2000) (requiring each Federal Department to improve access to Federally assisted programs and activities by persons with limited English proficiency and to implement a system by which individuals with limited English proficiency can meaningfully access the Departments' Federally conducted programs and activities).

[155] 80 FR at 54182 (citing *Lau*, 414 U.S. at 566) (reasoning that a federally funded educational program's failure to take affirmative steps to rectify the language deficiency of limited English proficient students of Chinese ancestry denies them a meaningful opportunity to participate in the educational program on the basis of their national origin).

[156] 65 FR at 52765.

[157] The Department's LEP Guidance provides an in-depth explanation of Title VI's prohibition against national origin discrimination as it affects limited English proficient populations and how recipients can determine what steps are reasonable to provide all individuals with limited English proficiency meaningful access. HHS LEP Guidance, *supra* note 49.

[158] Under Title VI, OCR investigates each complaint and conducts its compliance reviews on a case-by-case basis and tailors each case resolution to the particular facts of each case. For highlights of OCR's Title VI enforcement specific to the prohibition of national origin discrimination as it affects individuals with limited English proficiency, see Enforcement Success Stories Involving Individuals with Limited English Proficiency, U.S. Dep't of Health & Human Servs., Office for Civil Rights, *http://www.hhs.gov/ocr/civilrights/activities/examples/LEP/index.html* (last visited May 4, 2016).

[159] 80 FR 54172, 54183 (quoting HHS LEP Guidance, *supra* note 49, 68 FR at 47312).

[160] *Id.* (citing U.S. Dep't of Health & Human Servs., Agency for Health Care Research & Quality, Chapter 6, Patient Centeredness, National Healthcare Quality Report (2013), *http://www.ahrq.gov/research/findings/nhqrdr/nhqr13/chap6.html*). Person-centered and family centered care is one of the six priorities of the National Quality Strategy. Dep't. of Health & Human Servs., Agency for Health Care Research & Quality, 2014 National Healthcare Quality and Disparities Report, Person- and Family-Centered Care Chartbook, AHRQ Pub. No. 15–0007–14, at 3 (May 2015), *http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/2014chartbooks/personcentered/personcenteredcare-chartbook.pdf*.

[161] *Id.* at 54183 n.53 (stating that the Department's LEP Guidance takes a similar approach by identifying the factors that OCR will consider, in determining the extent of a recipient's obligations to individuals with limited English proficiency). *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47314–16.

In paragraph (b)(2)(iii), we provided that the prevalence of the primary language in which the individual with limited English proficiency communicates, among those eligible to be served or likely to be encountered by the health program or activity, might also be relevant.

In paragraphs (iv) and (v) of proposed § 92.201(b)(2)—the final illustrative factors listed—we noted that the resources available to the covered entity and the costs of language assistance services might also be relevant in a particular case.

In proposed paragraph (c), we clarified that language assistance services required under paragraph (a) must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency.[162]

Specific Requirements for Interpreter Services and Restricted Use of Certain Persons to Interpret or Facilitate Communication § 92.201(d) and (e)

In paragraphs (d) and (e), OCR proposed to codify standards described in the Department's LEP Guidance regarding qualified interpreters for individuals with limited English proficiency and the use of family members or friends as interpreters or to facilitate communication.[163] These proposed standards account for issues of competency, confidentiality, privacy, and conflict of interest that arise as a result of relying on informal (or ad hoc) interpreters. We noted that paragraphs (d) and (e) are consistent with oral interpretation standards that OCR has advanced through its resolution of Title VI cases and compliance reviews.[164]

Specifically, in paragraph (d), OCR proposed to address standards applicable to oral interpretation. We provided that when a covered entity is required by paragraph (a) to provide oral interpretation as a reasonable step to provide meaningful access to an individual with limited English proficiency, the covered entity must offer that individual a qualified interpreter.

In paragraph (e), we proposed restrictions on the use of certain persons to interpret or facilitate communication for an individual with limited English proficiency. We proposed that paragraph (e) apply in addition to, and regardless of, the appropriate level, type or manner of language assistance services a covered entity is required to provide. In paragraph (e)(1), we proposed to prohibit a covered entity from requiring an individual with limited English proficiency to provide his or her own interpreter. However, in paragraphs (e)(2)(i) and (ii), we proposed to identify narrow and finite situations in which a covered entity may rely on an adult accompanying an individual with limited English proficiency to interpret. In paragraph (e)(3), we proposed to prohibit a covered entity from relying on a minor child to interpret or facilitate communication and identified an exception to this prohibition that is narrower in scope than the exception identified in (e)(2)(i) and (ii).

We explained that in lieu of the approach we proposed in paragraphs (d) and (e), we considered proposing that all covered entities have the capacity to provide, in their health programs or activities, qualified interpreters for individuals with limited English proficiency through telephonic oral interpretation services available in at least 150 non-English languages. OCR invited comment on what oral interpretation services, if any, we should require and how such approaches appropriately balance the provision of meaningful access to individuals with limited English proficiency and covered entities' flexibility to identify the means of providing such access.

Acceptance of Language Assistance Services Not Required § 92.201(f)

In paragraph (f), we proposed that no individual with limited English proficiency should be required to accept language assistance services, consistent with an individual's right to self-determination. We provided that a covered entity cannot coerce an individual to decline language assistance services. We also provided that if an individual with limited English proficiency voluntarily declines an offer of language assistance services from the covered entity, a covered entity could denote, in the individual's file or records, the language assistance services offered and the declination.[165]

Alternative Approaches

In the proposed rule, we described alternate approaches we considered and requested comment on these approaches and any others to effectuate Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency. For instance, we noted that independent of the proposed requirements of § 92.201, covered entities, including Health Insurance Marketplaces, State agencies administering Medicaid and Children's Health Insurance Program (CHIP) programs, and qualified health plan issuers, must comply with any applicable language access requirements in other laws and regulations.[166] We invited comment on whether the requirements under different authorities should be harmonized and if so, to what extent and how.

We also stated that we considered a regulatory scheme requiring covered entities to provide meaningful access to each individual with limited English proficiency by providing effective language assistance services, at no cost, unless such action would result in an undue burden or a fundamental alteration of the health program or activity.[167]

We further noted that we considered a regulatory scheme requiring covered entities to provide a range of language assistance services in the non-English languages spoken by State-wide populations with limited English proficiency that meet defined thresholds. Such thresholds would provide a minimum number of non-English languages in which covered entities would be required to deliver oral interpretation services; to translate written vital documents and Web site content; and to include taglines on vital documents and on Web sites.[168] We requested comment on whether OCR should require thresholds, and if so, what thresholds should be required, and to what geographic areas or service areas the thresholds should apply. We also sought comment on whether OCR should permit covered entities to implement their obligations with a phased-in approach.

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[162] 80 FR at 54183 (citing HHS LEP Guidance, *supra* note 49, 68 FR at 47318, 47323 (with respect to privacy), 47316–17, 47322 (with respect to timeliness), and 47318–19, 47320, 47322 (with respect to services free of charge)).

[163] *Id.* at 54183–84 (citing HHS LEP Guidance, *supra* note 49, 68 FR at 47317–18, 47323).

[164] *See, e.g.,* HHS OCR VRA with Mee Memorial Hosp., *supra* note 82, at pt. II.J (defining qualified interpreter); HHS OCR VRA with Montgomery County DSS, *supra* note 82, at pts. II.E (defining qualifications of an "interpreter"), IV.H (requiring timely, competent language assistance), & IV.L (identifying interpreter standards).

[165] 80 FR at 54184 (citing HHS LEP Guidance, *supra* note 49, 68 FR at 47318, 47320 (suggesting that recipients consider whether to record the primary language of an individual with LEP or an individual's choice to provide his or her own interpreter)).

[166] The proposed rule discusses these entities' requirements at 80 FR at 54184–85.

[167] *Id.* at 54185.

[168] *See id.*

We also noted that we considered a regulatory scheme that would impose enhanced obligations on a subset of covered entities. We sought comment on what characteristics should define covered entities that could have enhanced obligations, such as whether the covered entity is of a certain type or size, has frequent contact with individuals with limited English proficiency, or operates particularly important health programs or activities, among other potential factors. We listed potential categories of covered entities that could have enhanced obligations, such as State agencies administering Medicaid or CHIP; Health Insurance Marketplaces; the Department in its operation of its health programs or activities; or covered entities that have a minimum number of beds, employees, or locations, such as hospitals, nursing homes or skilled nursing facilities, home health agencies, and retail pharmacies (including mail-order pharmacies).[169] We described that under this alternate approach, instead of evaluating each case on its particular facts, the Director would evaluate a covered entity's compliance based on whether the entity provided the range of language assistance services in the non-English languages specified.[170] We invited comment on this proposal.

We further requested comment on whether covered entities should be required to systematically prepare to provide language assistance services in their health programs or activities, such as through the establishment of policies and procedures or through other advance planning mechanisms. We stated that in OCR's experience, covered entities are in a better position to meet their obligations to provide language assistance services in a timely manner to individuals with limited English proficiency when those entities identify, in advance, the types and levels of services that will be provided in each of the contexts in which the covered entity encounters individuals with limited English proficiency.

OCR noted that an advance planning requirement could require each covered entity to identify all resources for providing language assistance services; annually assess the frequently-encountered or highly prevalent languages in the service area of the health program or activity; establish written procedures to which frontline staff could refer when encountering individuals with limited English proficiency; and monitor and oversee the quality of language assistance services provided. We also noted that an advance planning requirement could require each covered entity to build its capacity to provide language assistance services to meet the needs of the national origin populations that the entity serves. We requested comment on the types of advance planning mechanisms, if any, that should be required and why.

In the proposed rule, OCR advised that covered entities that are already developing or implementing language access plans, or otherwise assessing their language assistance needs, should continue such efforts. However, OCR stated that engaging in such planning is not a defense for failing to provide language assistance services to any particular individual at all, or in an untimely manner, if such services are reasonable steps to provide meaningful access. We advised that covered entities that are conducting advance planning should consider how they can ensure that language assistance services are available in their health programs and activities as they simultaneously improve their operational capacities to provide effective language assistance services into the future.

The comments and our responses regarding § 92.201 are set forth below:

Overall, commenters supported the proposed rule's inclusion of specific provisions addressing meaningful access for individuals with limited English proficiency. We received numerous comments written in non-English languages submitted by individuals with limited English proficiency who expressed how essential it is to have language assistance services, at no cost, to understand forms, invoices, and medication instructions. Many comments from the health care provider and insurance industry, as well as from organizations representing individuals with limited English proficiency, agreed that it is essential that individuals, regardless of national origin, be able to access covered entities' health programs and activities. We received many comments, however, regarding the scope and parameters of covered entities' obligations under the final rule.

Comment: Many commenters recommended revising the categories of individuals to whom a covered entity has an obligation to take reasonable steps to provide meaningful access. Specifically, commenters recommended that a covered entity's obligation should apply to those "eligible to be served" or "likely to be affected by" the covered entity's health programs and activities. Commenters suggested that proposed § 92.201(a), which stated that the obligation of a covered entity runs to those who the entity "serves or encounters in its health programs and activities," unduly narrowed the scope of the covered entity's obligation.

Response: In response to commenters' recommendations, we have replaced the phrase "that it serves or encounters" with "eligible to be served or likely to be encountered." We agree with commenters that a covered entity must be prepared to take reasonable steps to provide meaningful access to individuals beyond those who actually walk into, or contact, that entity. Where a covered entity is likely to encounter, but is unprepared to assist, individuals of particular national origin groups in the languages in which they communicate, those individuals are unlikely to seek services from, or participate in, the entity's health programs or activities, thereby perpetuating barriers to individuals' access to care.

We chose the phrase "eligible to be served or likely to be encountered" because it is one of the formulations in the HHS LEP Guidance of the population to which a covered entity has an obligation.[171] In addition, commenters' proposal that a covered entity's obligation applies to individuals "likely to be affected by" the covered entity's health programs and activities gave covered entities less concrete guidance about their obligations relative to the phrase "likely to be encountered."

Comment: Numerous commenters recommended that OCR revise the general obligation in § 92.201(a) to require that covered entities "provide meaningful access" to each individual with limited English proficiency rather than "take reasonable steps to provide meaningful access." Commenters explained that because "meaningful access" is already a subjective standard, requiring "reasonable steps to provide meaningful access" substantially dilutes covered entities' obligations to provide language assistance services.

These commenters suggested that language assistance should be provided in every situation and that oral interpretation, in particular, should be provided "on demand." Commenters suggested that the final rule make this basic obligation clear because some covered entities turn away individuals with limited English proficiency, stating that the entity does not provide language assistance services. For instance, one commenter shared that it is common for individuals with limited English proficiency to use a hospital emergency department as a source of primary care because the individuals' physicians do not offer qualified interpreters for individuals with limited English proficiency. Commenters also suggested that the Director's weighing of the illustrative factors set out in § 92.201(b) should focus exclusively on whether the covered entity provided the appropriate type, form, and manner of language assistance.

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[169] *See id.*

[170] *See id.*

[171] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47314, 47320, 47322.

Response: We decline to modify the general obligation in § 92.201(a) because it reflects familiar and longstanding requirements applicable under Title VI.[172] In addition, the regulatory scheme provides in 92.201(b)(1) that in assessing this standard, the Director will consider, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, which places covered entities on notice about the way in which we will evaluate the Title VI standard within the context of health programs and activities. OCR interprets the requirement that covered entities take "reasonable steps to provide meaningful access" to demand that each entity, as an initial step, assess the need to provide language assistance services to each individual with limited English proficiency and respond to that need by providing the appropriate language assistance services on a timely basis.

As we stated in the proposed rule, safe and quality health care requires an exchange of information between the health care provider and patient for the purposes of diagnoses, treatment options, the proper use of medications, obtaining informed consent, and insurance coverage of health-related services, among other purposes.[173] This exchange of information is jeopardized when the provider and the patient speak different languages and may result in adverse health consequences and even death.[174] Indeed, the provision of health care services, by its "very nature[,] requires the establishment of a close relationship with the client or patient that is based on sympathy, confidence and mutual trust,"[175] which cannot be established without effective communication.

Comment: Some commenters expressed concern about the potential financial and administrative burden to provide language assistance services. Many of these commenters expressed support for the proposed rule's inclusion of specific provisions addressing access for individuals with limited English proficiency but also urged that public and private health insurance issuers update medical codes and fee schedules to allow providers to receive reimbursement for the provision of language assistance services.

Some commenters offered proposals for minimizing the costs to covered entities for providing language assistance services—oral interpretation services in particular. These recommendations included that OCR facilitate access to telephonic oral interpretation, at no cost to covered entities, and that OCR ensure that covered entities have adequate funding to provide qualified interpreters for individuals with limited English proficiency.

Response: We appreciate hearing commenters' concerns and having the benefit of commenters' recommendations to lessen potential cost and administrative barriers that covered entities may face. It is beyond the scope of this rulemaking to adopt recommendations that OCR fund qualified interpreters or direct issuers to modify medical codes and fee schedules to reimburse health care providers for their provision of language assistance services.[176]

OCR encourages covered entities to work together to leverage their ability to provide language assistance services in the most cost-effective and efficient ways to meet their respective obligations under § 92.201(a) before using costs as a reason to limit language assistance services.[177] OCR also encourages professional associations and organizations to consider what role they can play in helping their members meet the requirements of § 92.201; we provided similar encouragement in the HIPAA Privacy Rule.[178]

We further remind State agencies receiving Federal financial assistance for Medicaid and the Children's Health Insurance Program that States may claim Federal matching funds for the costs of written translation and oral interpretation as administrative expenses or as medical assistance-related expenses.[179] Further, increased

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[172] *See Lau* v. *Nichols, supra* note 154 (interpreting Title VI to require the covered entity to take affirmative steps to provide students with limited English proficiency of Chinese origin with a meaningful opportunity to participate in Federally-funded educational programs); HHS LEP Guidance, *supra* note 49, 68 FR at 47313 ("[T]he failure of a recipient of [F]ederal financial assistance from HHS to take reasonable steps to provide LEP persons with [a] meaningful opportunity to participate in HHS funded programs may constitute a violation of Title VI and HHS's implementing regulations").

[173] 80 FR at 54183 (citing to the 2000 HHS LEP Guidance, *supra* note 49, 65 FR at 52763). *See generally* Cindy Brach et al., *Crossing the Language Chasm,* Health Affairs, vol. 24, no.2 424, at 424–25 (2005) (describing the impacts of language barriers in health care). In addition, the 2014 National Healthcare Quality and Disparities Report Chartbooks include metrics showing disparities between national origin groups, one of which expressly identifies trends of non-English speaking children who need health care for an illness, injury, or condition who sometimes or never got care as soon as wanted. *See* U.S. Dep't of Health & Human Servs., Agency for Health Care Research & Quality, 2014 National Healthcare Quality and Disparities Report, Chartbook on Health Care for Hispanics at 47, 57 (May 2015), *http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/2014chartbooks/hispanichealth/2014nhqdr-hispanichealth.pdf;* U.S. Dep't of Health & Human Servs., Agency for Health Care Research & Quality, Person- and Family-Centered Care Chartbook, *supra* note 160, at 12.

[174] 80 FR at 54183.

[175] *Id.*

[176] We note, however, that the Department's National Stakeholder Strategy for Achieving Health Equity identifies financing and reimbursement for "health interpreting services" as a strategy to achieve the goal of improving cultural and linguistic competency. *See* U.S. Dep't of Health & Human Servs., Office of Minority Health, National Partnership for Action to End Health Disparities. National Stakeholder Strategy for Achieving Health Equity, Section 3, 131 (2011), *http://minorityhealth.hhs.gov/npa/files/Plans/NSS/NSS_07_Section3.pdf.*

[177] We note, for example, that the Washington State Medicaid Interpreter Services Program centralizes the provision of language assistance services to achieve economies of scale. *See* Washington State Health Care Auth., Interpreter Services Program, *www.hca.wa.gov/medicaid/interpreterservices* (last visited May 4, 2016). Similarly, through OCR's Effective Communication in Hospitals Initiative, the Kentucky Hospital Association built the capacity to offer its approximately 120 member hospitals access to a telephonic interpretation service contract that offers a volume-based discount rate. *See* Kentucky Hospital Association, Effective Communication in Hospitals, *http://www.kyha.com/CM/Initiatives/Safety_and_Quality_Resources/Effective_Communication_in_Hospitals.aspx* (last visited May 4, 2016). Although OCR cannot certify that these approaches uniformly enable entities to meet the requirements of Section 1557, they do represent examples of the types of collaborative action that covered entities may consider.

[178] Standards for Privacy of Individually Identifiable Health Information, 65 FR 82462, 82749 (Dec. 28, 2000) (final rule) (codified at 45 CFR pts. 160 and 164) (encouraging professional associations to assist their members in developing policies and procedures required under the Privacy Rule); Standards for Privacy of Individually Identifiable Health Information, 64 FR 59918, 59992 (Nov. 3, 1999) (proposed rule) (encouraging professional associations to assist their members in developing policies and procedures required under the Privacy Rule).

[179] U.S. Dep't. of Health & Human Servs., Center for Medicare & Medicaid Servs., Increased Federal Matching Funds for Translation and Interpretation Services under Medicaid and CHIP 1 (Jul. 1, 2010), *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO10007.pdf* [hereinafter CMS

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funding may be available when States claim the cost of written translation and oral interpretation as administrative expenses if such language assistance services are provided for the "enrollment, retention, and use of services" for individuals with limited English proficiency eligible for CHIP and for Medicaid-eligible children and their families.[180] In addition, we remind qualified health plan issuers that the ACA requires, as a condition of an issuer's health plan receiving certification as a qualified health plan, that the issuer implement a quality improvement strategy for the qualified health plan that provides increased reimbursement or other incentives for the implementation of activities to reduce health and health care disparities, including through the use of language services.[181] We encourage health insurance issuers to structure their health plan payment structures to consider health care providers' expenses in providing language assistance services.

We decline to accept the recommendation that OCR facilitate access to telephonic oral interpretation services for all covered entities. Such facilitation is beyond the scope of the Federal government's role and is an impractical solution to address the needs of diverse Section 1557 covered entities. However, OCR does share best practices and useful resources, such as through the Federal government's Interagency Working Group on Limited English Proficiency, at *www.LEP.gov.*

Comment: We received numerous comments on whether the final rule should include an advance planning requirement for covered entities to be systematically prepared to provide language assistance services in their health programs and activities. The vast majority of these comments recommended that the final rule include such an advance planning requirement—specifically, the development and implementation of a language access plan that addresses the needs of the limited English proficient population in the service area of a covered entity's health program or activity. Commenters reasoned that a regulatory requirement is the most effective method of holding covered entities accountable for engaging in meaningful advance planning.

One commenter observed that many covered entities already evaluate the type of language assistance services they are obligated to provide, pursuant to the current HHS LEP Guidance, and thus that codifying this requirement would not impose a significant additional burden on covered entities. This commenter also asserted that an advance planning requirement is analogous to the approach of § 92.7, which requires certain covered entities to have a grievance procedure in place. Another commenter shared that in updating her employer's language access plan, the availability of online tools and resources greatly reduced the commenter's anticipated burden of what advance planning would require.

We received many comments recommending that the final rule identify specific required components of a language access plan, including the types of language access services the covered entity will provide and in what languages, based on the languages spoken by eligible individuals with limited English proficiency in the covered entity's service area. One commenter underscored that to increase efficiency and maximize cost savings, a language access plan should identify multiple types of language assistance services that a covered entity can use for different situations or even within one encounter. This commenter asserted that relying on just one kind of language assistance service may not be appropriate for all communications.

Another commenter recommended that the final rule mirror California's regulations on advance planning mechanisms for the provision of language assistance services.[182] This commenter stated that, consistent with California's regulations, OCR should require that language access plans identify all points of contact with individuals with limited English proficiency; provide a procedure for recording individuals' primary language; identify vital documents; provide a procedure for the translation of vital documents; provide a procedure to request translation of specific other documents; require training on language access services for all staff likely to have contact with individuals with limited English proficiency; require the assessment of the qualifications of bilingual/multilingual staff; and adopt written policies and procedures regarding the provision of language assistance services, including a procedure for contracting with language service vendors. Other commenters agreed that prior to using individuals to provide interpretation or translation services, covered entities should be required to evaluate or verify the individuals' knowledge, skills and abilities to confirm that they meet the definition of a qualified interpreter or a qualified translator for an individual with limited English proficiency.

We received a small number of comments opposing a requirement for advance planning. One commenter acknowledged that a language access plan is important in ensuring that covered entities are systematically prepared to provide language assistance services but recommended that OCR should merely encourage, not require, advance planning activities. The commenter observed that developing a language access plan may be too burdensome for small covered entities.

Response: Based on the comments received, we have added a factor—the only illustrative factor in § 92.201(b)(2)—that requires the Director to consider, if relevant, whether the entity has developed and implemented an effective written language access plan, appropriate to its particular circumstances. The language "appropriate to its particular circumstances" conveys our recognition that the nature and extent of the voluntary planning in which a covered entity may choose to engage will vary depending on the entity's particular health programs and activities, its size, its geographic location, and other factors. A language access plan need not be long, complex, or burdensome.

We note that a written language access plan has long been recognized as an essential tool to ensure adequate and timely provision of language assistance services, including compliance with the general obligation in § 92.201(a) and the quality standards in § 92.201(d)–(f). For instance, for over 15 years, Executive Order 13166 has required each Federal agency to create and implement a language access plan responsive to the needs of the limited English proficient population it serves.[183] Moreover, the

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Increased Federal Matching Funds]; *id.,* Recently Released Policy Guidance—CHIPRA and the ACA, Information Bulletin 1–2 (Jul. 9, 2010), *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/07-09-2010-CHIPRA-and-ACA.pdf* [hereinafter CMS Information Bulletin 7/9/10].

[180] CMS Increased Federal Matching Funds, *supra* note 179, at 1–2; CMS Information Bulletin 7/9/10, *supra* note 179, at 1–2; U.S. Dep't. of Health & Human Servs., Center for Medicare & Medicaid Servs., Information Bulletin 2 (Apr. 26, 2011), *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/Info-Bulletin-4-26-11.pdf.*

[181] *See* 42 U.S.C. 18031(c)(1)(E), (g)(1)(E) (describing qualified health plan certification requirements in a quality improvement strategy).

[182] *See* 28 CCR 1300.67.04(c) (requiring each health care service plan to develop and implement a language assistance program that contains standards for enrollee assessment; providing language assistance services; staff training; and compliance monitoring).

[183] E.O. 13166, 65 FR 50121 (2000). In 2011, the U.S. Department of Justice renewed the Federal Government's commitment to the Executive Order. Office of the Att'y General, U.S. Dep't of Justice, Federal Government's Renewed Commitment to Language Access Obligations Under Executive

development and implementation of a written language access plan is consistent with OCR's longstanding enforcement processes[184] and resolution agreements regarding Title VI.[185] Although we are not requiring language access plans, we encourage entities to consider whether and how they can engage in advance planning to facilitate their ability to meet their obligations under § 92.201 to serve individuals with limited English proficiency on a timely basis.

We decline to outline the minimum expectations for a language access plan, if a covered entity chooses to develop and implement one, because that approach would be too prescriptive. Nonetheless, in our experience, effective language access plans often, among other components, address how the entity will determine an individual's primary language, particularly if the language is an unfamiliar one; identify a telephonic oral interpretation service to be able to access qualified interpreters when the need arises; identify a translation service to be able to access qualified translators when the need arises; identify the types of language assistance services that may be required under particular circumstances; and identify any documents for which written translations should be routinely available. OCR remains available to covered entities as a resource for technical assistance in the development and implementation of language access plans in their health programs and activities. HHS offers helpful guidance on this subject,[186] as does the U.S. Department of Justice.[187] We encourage covered entities to refer to these materials to assist their advance planning activities.

Comment: Many commenters recommended modifications to, and additional clarification regarding, the list of factors that the Director will take into account, if relevant, among other relevant factors in evaluating a covered entity's compliance with its general obligation in § 92.201(a). These comments fall into four main categories. First, many commenters requested that we add additional factors to the list in § 92.201(b)(2)(i)–(v). Commenters were concerned that absent explicit references to these factors, the Director would not, or could not, consider them. Examples of factors that commenters requested that we add include:

- The frequency with which a covered entity encounters, or is likely to encounter, a particular non-English language;
- the impact to the consumer if language assistance services are not provided;
- the extent to which covered entities can lessen their own cost burdens through technology and reasonable business practices, if the Director considers the costs of language assistance services; and
- if and when a covered entity is permitted to choose a less costly language assistance service than the one an individual may request.

Second, many commenters recommended that we combine the "costs of language assistance services" in proposed § 92.201(b)(2)(v) with "[a]ll resources available to the covered entity" in proposed § 92.201(b)(2)(iv) into a single factor because the two are inherently intertwined.

Third, some commenters requested that OCR clarify in the final rule how the factors in proposed § 92.201(b)(2)(i)–(v) would be weighted relative to each other, if relevant and thus evaluated by the Director in a given case. Most commenters who requested clarification recommended that the costs of language assistance services and the resources available to the covered entity not be weighted more heavily than the other factors or become dispositive.

Fourth, a number of commenters requested clarification on the function that the length and complexity of the communication in proposed § 92.201(b)(2)(i) would have in the Director's evaluation of a particular case.

Response: After considering the comments received, we have revised the final rule to eliminate the illustrative factors and to articulate only one factor: Whether a covered entity has developed and implemented an effective written language access plan appropriate to its circumstances. We agree with some commenters' concerns that including multiple illustrative factors in the regulatory text may create the erroneous impression that the Director will not consider relevant factors absent from § 92.201(b)(2). Were OCR to modify § 92.201(b)(2) to include all factors suggested by commenters, however, the long list of factors might unintentionally create an unworkable regulatory scheme in the attempt to capture any possible factor that might be relevant in some circumstances.

Given these concerns, § 92.201(b)(1)–(2) of the final rule requires the Director to evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue to the individual with limited English proficiency, and requires the Director to take into account all other relevant factors, including whether the entity has developed and implemented an effective language access plan. We have identified this factor in particular to provide a concrete reminder to covered entities that they may wish to take action to prepare to provide language assistance services to the individuals with limited English proficiency that they will serve or encounter. We reiterate, however, that adoption of a language access plan is a voluntary measure that is not required by the rule; we will continue to evaluate, on a case-by-case basis, whether entities have taken reasonable steps to provide meaningful access and will evaluate all relevant factors in making that assessment.

We recognize that the absence of illustrative factors in regulation text may diminish clarity regarding the Director's evaluation of a covered entity's compliance with § 92.201(a). To provide guidance to covered entities on our intended interpretation of § 92.201(b)(2) and to be responsive to

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Order 13166 (Feb. 17, 2011) *https://www.justice.gov/crt/about/cor/AG_021711_EO_13166_Memo_to_Agencies_with_Supplement.pdf.*

[184] For example, as part of the certification process to ensure that recipients of Medicare Part A are in compliance with Title VI, OCR requires Medicare Part A providers to document their written procedures on communicating effectively with individuals with limited English proficiency. U.S. Dep't of Health and Human Servs., Office for Civil Rights, Civil Rights Information Request for Medicare Certification, Form OMB No. 0945–0006, pt. II.7, *http://www.hhs.gov/sites/default/files/ocr/civilrights/clearance/ocr_mctap.pdf* (identifying written policies and procedures with respect to serving individuals with limited English proficiency as required in a provider's application for Medicare certification).

[185] *See, e.g.,* HHS OCR VRA with Mee Memorial Hosp., *supra* note 82, at pt. IV.B (requiring the development and implementation of a language access policy), pt. IV.C.1 (determining the language needs of the affected population), pt. IV.C.2 (determining the language needs of each individual with limited English proficiency); HHS OCR VRA with Montgomery County DSS, *supra* note 82, at pt. IV.B (requiring the development and implementation of a language access policy), pt. IV.C.1 (determining the language needs of the affected population), pt. IV.C.2 (determining the language needs of each individual with limited English proficiency).

[186] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47319–21 (encouraging recipients to develop a language access plan [called an "LEP Plan" in the Guidance]). HHS's updated language access plan may be a useful model for covered entities. *See* U.S. Dep't of Health & Human Servs., Language Access Plan (2013), *http://www.hhs.gov/sites/default/files/open/pres-actions/2013-hhs-language-access-plan.pdf.*

[187] *See* U.S. Dep't of Justice, Civil Rights Div., Language Access Assessment and Planning Tool for Federally Conducted and Federally Assisted Programs (May 2011), *http://www.lep.gov/resources/2011_Language_Access_Assessment_and_Planning_Tool.pdf. See also* the Federal government's Interagency Working Group on Limited English Proficiency, at *www.LEP.gov.*

comments received on the illustrative factors proposed, the following preamble discussion sets forth a range of factors that may be relevant in any given case.[188]

As an initial matter, we note that one of the factors commenters recommended we add, which is the impact to the individual of failing to provide language assistance services, is necessarily encompassed within § 92.201(b)(1) regarding an evaluation of the nature and importance of the health program or activity and the particular communication at issue.[189]

Factors that may be relevant in a particular case for the Director to consider pursuant to § 92.201(b)(2) include but are not limited to: the length, complexity, and context of the communication; the prevalence of the language in which the individual communicates among those eligible to be served or likely to be encountered by the health program or activity; the frequency with which a covered entity encounters the language in which the individual communicates; whether a covered entity has explored the individual's preference, if any, for a type of language assistance service, as not all types of language assistance services may work as well as others in providing an individual meaningful access to the covered entity's health program or activity; the cost of language assistance services and whether a covered entity has availed itself of cost-saving opportunities; and all resources available to the covered entity, including the entity's capacity to leverage resources among its partners or to use its negotiating power to lower the costs at which language assistance services could be obtained.

We decline to adopt commenters' suggestions to create a regulatory scheme that assigns particular weight to any specific relevant factor because the Director will consider and weigh all relevant factors pursuant to § 92.201(b)(2) on a case-by-case basis.

Because we have eliminated the factors in proposed 92.201(b)(2)(i)–(v), it is moot whether OCR should combine the proposed factor on the costs of language assistance services with the proposed factor on resources available to the covered entity. Nevertheless, costs and resources are intertwined, which is a principle reflected in the HHS LEP Guidance with respect to Title VI[190] and a principle we reiterated with respect to Section 1557 in the proposed rule.[191]

With respect to commenters' requests for clarification on the relevance that the length and complexity of a particular communication has on the type of language assistance a covered entity should provide, we note that this factor is emblematic of the fact-based nature of the inquiry described in § 92.201(b)(1)–(2). Where a document is long and complex, it may in some cases be necessary for a covered entity to provide a written translation so that an individual with limited English proficiency can refer back to or study it at a later time. In other cases, however, a covered entity may meet the requirements of this section by summarizing the document orally for a qualified interpreter to then convey to the individual with limited English proficiency, if such approach is sufficient to provide the individual with limited English proficiency meaningful access to the information.[192]

Comment: Many commenters supported the requirement in proposed § 92.201(c) that a covered entity provide language assistance services to an individual with limited English proficiency in a timely manner. Some commenters further suggested that the final rule set out specific time frames for the provision of oral interpretation, written translation, and taglines. For instance, some commenters recommended that we revise § 92.201(c) to require oral interpretation immediately upon request, written translations within 30 days after the English version is finalized, and taglines simultaneously with English documents. These commenters asserted that oral telephonic interpretation services should be available, at a minimum, no more than 30 minutes after a covered entity encounters an individual with limited English proficiency.

Response: We decline to include prescriptive timeframes for the provision of language assistance services. There is no one definition of "timely" that applies to every type of interaction with every covered entity at all times. Consequently, consistent with the overarching framework of § 92.201, a determination of whether language assistance services are timely will depend on the specific circumstances of each case. We reiterate our statement from the proposed rule that language assistance is timely when it is provided at a place and time that ensures meaningful access to persons of all national origins and avoids the delay or denial of the right, service, or benefit at issue.[193]

Comment: Some commenters suggested that the final rule prohibit the use of computer-automated translation. These commenters suggested that reliance on automated translation is not accurate for the highly specialized vocabulary and terminology used in the health care and health insurance settings, especially for less common non-English languages.

Response: We decline to codify a prohibition on the use of automated translation as part of the final rule because such a requirement may unintentionally stifle innovation in this rapidly developing area. Furthermore, depending on the language at issue as well as the content of the translation, some translation technologies are advantageous to facilitate the translation of written content when used along with a qualified translator who independently verifies the accuracy and quality of the translation.[194] For

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[188] Some of these factors were proposed in § 92.201(b)(2)(i)–(v), were suggested by commenters', are grounded in the HHS LEP Guidance, or are staples of the effective communication analysis in § 92.202 of this final rule, consistent with Federal disability rights law.

[189] *See* HHS LEP Guidance, *supra* note 49, 68 FR 47311, at 47315 (describing how and why a recipient of Federal financial assistance should consider the nature and importance of the program or activity in determining the extent of its language access obligations under Title VI).

[190] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47315 ("Resource and cost issues, however, can often be reduced by technological advances; the sharing of language assistance materials and services among and between recipients, advocacy groups, and Federal grant agencies; and reasonable business practices." "Large entities and those entities serving a significant number or proportion of LEP persons should ensure that their resource limitations are well-substantiated before using this factor as a reason to limit language assistance.").

[191] *See* 80 FR at 54183.

[192] A third party to the communication, such as a qualified interpreter for an individual with limited English proficiency, would orally interpret the covered entity's oral summary from English to a non-English-language and would not alter, summarize, omit, or distort the oral summary that the covered entity provides or judge which information is relevant or important. *See e.g.,* The Nat'l Council on Interpreting in Health Care, A National Code of Ethics for Interpreters in Health Care 8, 13 (2004), *http://www.ncihc.org/assets/documents/publications/NCIHC%20National%20Code%20of%20Ethics.pdf* (discussing the ethical principle of fidelity to the original message).

[193] 80 FR 54172, 54183. The National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards) emphasize the importance of timely language assistance. U.S. Dep't of Health & Human Servs., Office of Minority Health, The National CLAS Standards, *http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53* (last visited May 4, 2016).

[194] Jessica Sperling, Migration Policy Institute, Communicating More for Less: Using Translation and Interpretation Technology to Serve Limited English Proficient Individuals (2011), 12 *http://www.migrationpolicy.org/research/communicating-more-less-using-translation-and-interpretation-technology-LEP* (noting that translation memory programs are used in the public and private sector to increase the efficiency of translating a high-

instance, translation memory software stores segments of previously translated phrases and can improve a qualified translator's efficiency, especially when updating documents.[195]

We do, however, agree with commenters' concerns regarding the use of some automatic translation technologies, which "is particularly dangerous, and can lead to very serious misunderstandings and adverse consequences for medical documents."[196] For example, machine translation programs translate text by performing simple substitution of words using statistical techniques, which may produce highly unreliable translations for certain languages and written content.[197] As a result, using automated translation as the only tool for translating written documents would fulfill a covered entity's obligation under § 92.201(a) only if a qualified translator reviewed the translation for accuracy and edited it as needed.[198] OCR encourages covered entities to understand the strengths and weaknesses of the technology and software programs that qualified translators use.[199]

Comment: Commenters identified that some covered entities lack policies or practices to confirm or evaluate a staff member's skills as a qualified translator or to serve as a qualified interpreter for an individual with limited English proficiency. For instance, commenters stated that they are aware of situations where individuals who are qualified to interpret—but not translate—are nonetheless translating complex documents such as informed consent forms and discharge instructions. Comments recommended that the final rule require covered entities to evaluate staff members' non-English language proficiency and other skills to ensure that they are qualified before permitting them to interpret, translate, or communicate with individuals with limited English proficiency in the individuals' primary languages.

Response: We share commenters' concerns and, in response, have modified the rule in two ways. First, the final rule requires a covered entity to use a qualified translator for translating written content with respect to its health programs and activities. As the Department stated in its LEP Guidance, "[t]he permanent nature of written translations [ ] . . . imposes additional responsibility on the recipient to take reasonable steps to determine that the quality and accuracy of the translations permit meaningful access by LEP persons."[200] We broadened the title of § 92.201(d) to reflect that this paragraph now addresses specific requirements for written translation in addition to oral interpreter services. The text in proposed paragraph (d) addressing specific requirements for oral interpretation is now reflected as paragraph (d)(1); new paragraph (d)(2) addresses the use of qualified translators.

Second, we added a new paragraph (4) to § 92.201(e) to restrict covered entities from relying on staff who do not meet the definition of "qualified bilingual/multilingual staff" in § 92.4. In OCR's enforcement experience, covered entities too frequently rely on staff members who possess only a rudimentary familiarity speaking and understanding a non-English language (for example relying on their "high school" level of language proficiency) to communicate with individuals with limited English proficiency. This can result in miscommunication and the omission of relevant information, which can in turn result in a lower standard of care and raise questions about whether consent provided by an individual with limited English proficiency was truly informed. Similarly, we have found that qualified bilingual staff members sometimes serve as interpreters even though they do not possess the non-verbal skills of interpreting nor adhere to generally accepted principles of interpreter ethics.

Comment: Some commenters recommended that the final rule not restrict covered entities from relying on friends or family of individuals with limited English proficiency to provide oral interpretation, even when the companion is a minor. These commenters noted that some individuals with limited English proficiency prefer to use their companions to interpret; they also observed that minor children are frequently involved in many aspects of their parents' health care; accordingly, commenters stated that awareness of their parents' health care needs may equip children of individuals with limited English proficiency to act as patient advocates for their parents.

In contrast, numerous commenters supported the proposed rule's standards for oral interpretation and the proposed restrictions on certain persons to interpret or facilitate communication. For instance, one health care provider shared that a high risk hospital was unprepared to provide oral interpretation to a woman in labor. The patient's child had to interpret what her mother was saying but the child did not know the proper terminology to understand the provider's medical questions about a fatal high risk condition.

In addition, many commenters who are limited English proficient shared that some covered entities have required individuals to bring their own interpreters, at a cost to the individual. Others shared that family members and children have served as interpreters for them, which has been insufficient because such family members and children do not have the requisite skills to interpret accurately.

Response: We decline to eliminate the specific requirements in § 92.201(d)-(e) of the proposed rule regarding oral interpretation or the restrictions on certain persons to facilitate communication or interpret. Commenters' recommendations run contrary to HHS's longstanding guidance under Title VI[201] and to OCR's experience and enforcement practices.[202] In many circumstances,

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volume of documents and to assist a qualified translator in improving consistency among translated documents).

[195] *Id.*

[196] Int'l Medical Interpreters Assoc., IMA Guide on Medical Translation, *supra* note 85, at 3.

[197] *Id.* at 3; EM Balk et al., Assessing the Accuracy of Google Translate To Allow Data Extraction From Trials Published in Non-English Languages, (Prepared by the Tufts Evidence-based Practice Center for the Agency for Healthcare Research & Quality, U.S. Dep't of Health & Human Servs.), 12–15, 21- 24, Pub. No. 12(13)–EHC145–EF (2013), *https://www.effectivehealthcare.ahrq.gov/ehc/products/329/1386/Methods_Paper-Google-Translate_1-17-13.pdf*.

[198] This position is consistent with the position on this issue taken by the U.S. Department of Justice and the U.S. Department of Education. *See* U.S. Dep't of Justice & U.S. Dep't of Educ., Dear Colleague Letter: English Learner Students and Limited English Proficient Parents, 38 n.103 (Jan. 7, 2015), *http://www2.ed.gov/about/offices/list/ocr/letters/colleague-el-201501.pdf*.

[199] For considerations on ensuring the quality of translations, see Kleber Palma, Migration Policy Institute, Strategies to Help Covered Entities Ensure Quality of Translations, *http://www.migrationpolicy.org/programs/language-access-translation-and-interpretation-policies-and-practices/practitioners-corner* (last visited Mar. 23, 2016); Jessica Sperling, Migration Policy Institute, Practitioner's Corner: Drafting Request for Proposals and Contracts for Language Assistance Services, *http://www.migrationpolicy.org/programs/language-access-translation-and-interpretation-policies-and-practices/practitioners-corner-drafting* (last visited May 4, 2016).

[200] HHS LEP Guidance, *supra* note 49, 68 FR at 47317.

[201] HHS LEP Guidance, *supra* note 49, 68 FR at 47317–18, 47323.

[202] *See, e.g.*, Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and the Rhode Island Department of Human Services, OCR Transaction No. 0876828, pt. IV.K. (Jan. 19, 2011) *http://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/ridhhsagreement.pdf* (containing restrictions on the use of family members and friends as interpreters).

family members, friends, and especially children, are not competent to provide quality, accurate oral interpretation. For communications of particularly sensitive information, oral interpretation by an individual's family or friend often also implicates issues of appropriateness, confidentiality, privacy, and conflict of interest. Thus, covered entities may not rely on family members, friends, or other informal interpreters to provide language access services unless the situation meets an applicable exception in § 92.201(e)(2)-(3) of the final rule. This exception sufficiently balances an individual's preferences with an interest in ensuring competent language assistance services by allowing individuals to use accompanying adults to interpret in some circumstances.

Comment: One commenter suggested that entities should be exempt from complying with the HIPAA Privacy Rule when providing a qualified interpreter for an individual with limited English proficiency when required under § 92.201(a) of this final rule. Specifically, the commenter was concerned that Section 1557 covered entities would be forced to use or disclose protected health information in violation of the Privacy Rule when engaging interpreter services.

Response: OCR is responsible for enforcing the HIPAA Privacy Rule in addition to the rule implementing Section 1557. We note that, in most instances, a qualified interpreter will be a business associate or a workforce member of the covered entity. If a qualified interpreter is a business associate, a covered entity may disclose protected health information to the qualified interpreter if it obtains satisfactory assurances that the interpreter will use the information only for the purposes for which the interpreter was engaged and will safeguard the information from misuse. Such satisfactory assurances must be in writing and in the form of a contract between the covered entity and the qualified interpreter. If a qualified interpreter is a workforce member of the covered entity, a covered entity may share information with that interpreter as an employee or another type of agent of the entity (*e.g.*, hired through a contract or on the covered entity's staff as a volunteer).

Determining the relationship between the interpreter and the covered entity is a covered entity's HIPAA obligation and is unchanged by Section 1557 or this part. We encourage covered entities to review OCR's HIPAA Frequently Asked Questions (FAQ) regarding business associates at *http://www.hhs.gov/ocr/privacy/hipaa/faq/business_associates/760.html*, and OCR's HIPAA FAQ regarding interpreters at *http://www.hhs.gov/hipaa/for-individuals/faq/528/can-my-health-care-provider-discuss-my-health-information-with-an-interpreter/*.

Comment: A few commenters suggested that the final rule urge covered entities to provide an in-person qualified interpreter for an individual with limited English proficiency as the default type of oral interpretation. These commenters explained that covered entities should rely on remote interpretation via telephone or video only in urgent situations or if an in-person interpreter is unavailable. These commenters reasoned that use of remote interpretation technologies may miss nuances of the communication and result in less accurate or less comprehensible communication. A few commenters recommended that a covered entity's use of remote interpretation services, via phone or video, be limited to administrative matters that can be addressed in 10 minutes or less. Moreover, in response to comments received in 2013 on OCR's Request for Information on Section 1557, some commenters identified concerns with the use of video remote interpretation services because the video connections used often were of a poor quality.

Response: We believe that commenters' recommendations regarding restrictions on remote oral interpretation are unnecessarily prescriptive and inconsistent with the fact-based, contextualized analysis under Title VI and this final rule. However, in situations where visual cues and other messages depend on physical as well as verbal communication, remote interpretation may not be adequate to provide meaningful access to an individual with limited English proficiency.

To address concerns that video remote interpreting technologies may result in less comprehensible communication, we are setting performance standards in § 92.201(f) of this final rule for video remote interpreting services [203] used for oral interpretation for an individual with limited English proficiency. These standards are designed to achieve parity with the regulation in the disability rights context regarding video remote interpreting technologies. Thus, the standards in § 92.201(f)(1)-(4) of the final rule closely parallel the standards on video remote interpreting services in § 92.202 regarding effective communication for individuals with disabilities, which in turn rely on the standards under Title II for the use of sign language interpreters.[204]

Comment: We received a few comments expressing concern about proposed § 92.201(f), re-designated in the final as § 92.201(g), which provides that an individual with limited English proficiency shall not be required to accept language assistance services offered by a covered entity. Some commenters recommended that proposed § 92.201(f) permit a covered entity to require the presence of a qualified interpreter, even if an individual with limited English proficiency has declined language assistance services.

Commenters suggested that when the individual who declines language assistance services is a patient, the health care provider's ability to accurately diagnose medical conditions is undermined. Commenters similarly stated that when the individual who declines language assistance services is a limited English proficient health care decision-maker for a child, that decision-maker would not be able to appropriately consent to, or participate in, a child's treatment plan. These commenters recommended requiring that a covered entity's insistence on a qualified interpreter be made in a non-coercive and culturally-appropriate manner.

Response: OCR interprets proposed § 92.201(f), which this final rule re-designates as § 92.201(g), to allow a covered entity to use a qualified interpreter when it is a reasonable step to provide an individual with limited English proficiency access to the covered entity's health program or activity. Although an individual with limited English proficiency can decline a qualified interpreter for herself, nothing in the rule is intended to bar a provider from using a qualified interpreter to assist the provider in communicating with, and assuring appropriate treatment to, the individual.[205] As a result, OCR does not intend for § 92.201(g) of the final rule to restrict a covered entity from using a qualified interpreter in either of the situations commenters raised. We also remind covered entities that, as we stated in the proposed rule, they may not discourage individuals with limited English proficiency from accepting language assistance services.

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[203] We intend that "video remote interpreting services" used for oral interpretation for individuals with limited English proficiency means the same that it does when used to provide interpretation for individuals with disabilities as defined by reference in § 92.4 of this final rule: "an interpreting service that uses video conference technology over dedicated lines or wireless technology offering high-speed, wide-bandwidth video connection that delivers high-quality video images as provided in [28 CFR] 35.160(d)." *See infra* § 92.4 (defining "auxiliary aids and services" to include "video remote interpreting services," as defined in Title II of the ADA, 28 CFR 35.104).

[204] 28 CFR 35.160(d)(1)–(4). In contrast to 28 CFR 35.160(d)(2), which regulates the size of the video image to ensure that the screen shows one's face, arms, hands, and fingers, paragraph (f)(2) of § 92.201 in this final rule does not regulate the size of the video image because this component is less relevant for oral interpretation between English and non-English languages.

Comment: Some commenters proposed that OCR regulate the data sources to which covered entities may refer to assess the prevalence of languages spoken by individuals with limited English proficiency in their respective service areas. Commenters also recommended that OCR provide covered entities with resources, such as data-driven maps of languages spoken by limited English proficient populations in their respective service areas, to facilitate covered entities' assessments.

Response: We decline to accept commenters' suggestions, but we support covered entities' efforts to assess the language needs of their respective service areas. An assessment is a foundational best practice for a language assistance services program.[206] Data sources that may be useful include data from the United States Census Bureau, particularly the American Community Survey; utilization data from the covered entity's files for individuals with limited English proficiency; data from State and local governments; school system data; data from community agencies and organizations; and data from refugee or immigrant serving agencies.[207] Covered entities, however, are in the best position to determine what local or regional data sources are best suited to their needs. When using any data source, covered entities should look at the reliability, stability, and currency of the data to understand its strengths and weaknesses.

Comment: Many commenters provided feedback on OCR's request for comments on whether the final rule should set thresholds for the non-English languages in which covered entities must provide a range of language assistance services. The majority of comments on this issue focused on thresholds for the translation of vital documents.

Commenters supporting thresholds for written translation suggested that this policy improves access for individuals with limited English proficiency; streamlines OCR's compliance determinations; eliminates ambiguity by providing clear, quantifiable standards for covered entities; is consistent with other Departmental regulations specifying thresholds for written translation; and mitigates the risk that covered entities forgo written translation entirely.

Commenters recommended a variety of thresholds, such as those requiring translation based on the number of languages, percentage of language speakers, or the number of language speakers in a covered entity's service area, or composite thresholds mixing and matching these approaches. Some commenters simply stated that vital documents should be translated into the most commonly encountered languages in a covered entity's service area. Others suggested that OCR codify the threshold for translation of vital documents that is articulated as a safe harbor in the HHS LEP Guidance: translation into languages spoken by at least 1,000 persons or at least 5% of those present in the service area.[208] Other commenters asserted that numeric thresholds for translation are too rigid to be applied universally, and recommended that the final rule focus on translating materials for certain health programs, such as clinical research or health insurance programs.

Response: Although we have extensively considered whether to include thresholds for written translation and/or oral interpretation as either a safe harbor or as an across-the-board minimum requirement, we decline to set such thresholds in the final rule. First, although thresholds may improve access for some national origin populations, the approach does not comprehensively effectuate Section 1557's prohibition of national origin discrimination. Setting thresholds would be both under-inclusive and over-inclusive, given the diverse range, type, and sizes of entities covered by Section 1557 and the diverse national origin populations within the service areas of entities' respective health programs and activities.

For instance, a threshold requiring all covered entities, regardless of type or size, to provide language assistance services in languages spoken by 5% of a county's limited English proficient population could result in the provision of language assistance services in more languages than the entity would otherwise be required to provide under its obligation in § 92.201(a). This threshold would apply regardless of the number of individuals with limited English proficiency who are eligible to be served or likely to be encountered by the covered entity's health program or activity and regardless of the covered entity's operational capacity. Similarly, this threshold could leave behind significant numbers of individuals with limited English proficiency, served by a covered entity's health program or activity, who communicate in a language that constitutes less than 5% of the county's limited English proficient population.

Although some Departmental regulations set thresholds, those regulations address entities or health programs of similar sizes and types, such as qualified health plan issuers, Marketplaces, Medicare Advantage, and Medicare Part D. In comparison, Section 1557 and this part regulate more diverse types of covered entities with potentially more diverse limited English proficient populations. We are concerned that significant limited English proficient populations might receive no or inadequate language assistance services under a threshold-based regulation. We are also concerned about the burden an across-the-board translation threshold might place on small covered entities.

Moreover, we value the flexibility inherent in the contextualized approach we have chosen to assess compliance with the requirement to take reasonable steps to provide meaningful access. We thus decline to impose the prescriptive standards recommended by the commenters as inconsistent with this customized regulatory approach.

Comment: We received many comments in response to whether the rule should require enhanced language access obligations for some types of covered entities and if so, what types of entities should be subject to enhanced obligations. Some commenters suggested that enhanced obligations would be appropriate for certain covered entities that offer particularly significant or large health programs or activities, such as the Department, State agencies administering Medicaid or CHIP, Marketplaces, and qualified health plan issuers. These commenters asserted that these covered entities possess both the resources and the means to meet enhanced obligations and that they can leverage economies of scale. The commenters also asserted that imposing enhanced obligations on these entities would benefit smaller entities by making translated documents more widely available.

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[205] This understanding is consistent with the HHS LEP Guidance, *supra* note 49, 65 FR at 47318 (stating that even if an individual with limited English proficiency declines a qualified interpreter, where precise, complete, and accurate information is critical, or where the competency of the preferred interpreter that the individual desires to use is not established, "a recipient may want to consider providing its own, independent interpreter, even if the LEP person wants to use his or her own interpreter as well.").

[206] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47314, 47320.

[207] *See* Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Memorial Health System, OCR Transaction No. 08–79513, pt. V.B.1.b, *http://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/mhs_vra.pdf* (last visited Mar. 11, 2016) (listing data sources for an assessment of language needs).

[208] The safe harbor further provides that if a language group with fewer than 50 individuals constitutes 5% of the recipient's service area, the recipient is not obligated to translate written materials but must provide written notice in the primary language of that language group of the right to receive oral interpretation, at no cost to the individual. HHS LEP Guidance, *supra* note 49, 68 FR at 47319.

Commenters also addressed the scope of enhanced language access obligations, suggesting that such obligations should include requiring oral interpretation in at least 150 languages and the translation of documents into languages spoken by individuals with limited English proficiency when such individuals constitute 5% of, or 500 people in, the State population or the covered entity's service area.

A few commenters opposed enhanced language access obligations for certain types of covered entities. Specifically, one commenter asserted that there was no principled reason for retail pharmacies, which the proposed rule listed as an example of a covered entity that could have enhanced obligations under § 92.201,[209] to be subject to enhanced language access obligations.

Response: We reiterate our view that the contextualized approach in § 92.201 best considers both the needs of individuals with limited English proficiency and the potential burden on covered entities. Creating uniform, across-the-board requirements for particular categories of covered entities is, like thresholds, both under-inclusive and over-inclusive. For example, some smaller entities may operate in areas with significant concentrations of individuals with limited English proficiency; these entities may need to provide a broader scope of language assistance services to meet the requirements of § 92.201 than do other entities of similar size in less diverse areas. Similarly, State agencies that administer Medicaid and CHIP programs will differ with respect to the size and diversity of the limited English proficient populations they serve and the resources available to them.

Comment: Some commenters asserted that HHS, other Federal Departments, and States already heavily regulate health insurance issuers covered by Section 1557, thus subjecting them to multiple language access regulations at the State and Federal level. These commenters recommended two policy approaches to streamline Federal and State language access requirements: (1) Harmonize nondiscrimination rules across all Federal and HHS programs to create a national standard; and/or (2) permit a deeming approach that allows compliance with Federal or State language access laws to suffice for compliance with Section 1557, and similarly allow compliance with Section 1557 to suffice for compliance with other Departmental regulations addressing language access. In contrast, numerous commenters supported our fact-specific, contextualized approach and urged consideration of additional factors (*see* discussion *supra*) that would require the more robust provision of language assistance services.

Response: The Department understands the potential for confusion and burden that can be imposed where entities are subject to multiple sets of overlapping requirements. For this reason, we have harmonized, to the extent possible, the tagline requirement in § 92.8(d)(1) with the tagline requirement applying to Marketplaces and qualified health plan issuers under 45 CFR 155.205(c)(2)(iii)(A).[210] We will continue to coordinate as appropriate within HHS and with other Federal departments to ensure that the application and enforcement of requirements under Section 1557 is consistent with other provisions of Federal law or regulations.

However, we decline to adopt an approach that otherwise automatically harmonizes nondiscrimination rules or deems compliance with other laws sufficient for compliance with Section 1557. As we noted above in the discussion of deeming in the General Comments, it is common for entities to be subject to multiple State and Federal regulations, even when some of those regulations have been adopted by a single Federal agency. Indeed, even under CMS regulations for instance, Health Insurance Marketplaces,[211] State agencies administering Medicaid and CHIP programs,[212] and qualified health plan issuers,[213] are subject to multiple differing requirements with regard to language assistance services.

With specific regard to language assistance services, there are likely numerous situations in which a qualified health plan issuer's compliance with the meaningful access provisions of 45 CFR 155.205(c) would suffice to meet the requirements of Section 1557; indeed, there are instances in which 45 CFR 155.205(c) (*e.g.*, requiring that Marketplaces and qualified health plan issuers provide telephonic oral interpretation in 150 languages[214]) might require more than would be required in a particular case under the fact-based analysis we adopt for Section 1557. However, we are concerned that there may be cases in which using CMS regulations alone to define a covered health insurance issuer's obligations could leave significant numbers of individuals with limited English proficiency without any, or adequate, access to language services.

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[209] *See* 80 FR at 54185.

[210] Qualified health plan issuers are also bound by the tagline requirement in market-wide regulations at 45 CFR 147.136(e) (effective Jan. 19, 2016) described in the preamble to § 92.8, *supra* note 107.

[211] Health Insurance Marketplaces have language access obligations under laws independent of Federal civil rights laws requiring the following to be accessible to individuals with limited English proficiency: a Marketplace's toll-free call center, *see* 45 CFR 155.205(a); a Marketplace's Web site, *see id.* 155.205(b); applications, forms, and notices required to be sent by a Marketplace^{SM}; *see id.* 155.230(b); and a Marketplace's consumer assistance functions, including a Marketplace's outreach and education activities and a Marketplace's Navigator program authorized by 42 U.S.C. 18031(i) and regulated at 45 CFR 155.210, *see id.* 155.205(d) and (e). In making information accessible to individuals with limited English proficiency, Marketplaces must do so through a combination of written translation, oral interpretation, posting of taglines, and translation of certain Web site content. *See* 45 CFR 155.205(c)(2)(i)(A) (oral interpretation), (ii) (written translation), (iii)(A) (taglines), (iv)(A) (translation of certain Web site content). With respect to a Marketplace's Navigator program, Navigators are required to provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Marketplace^{SM}, including individuals with LEP. *See* 42 U.S.C. 18031(i)(3)(E) (statutory requirement); 45 CFR 155.210(e)(5) (regulatory requirement).

[212] State agencies administering Medicaid programs and CHIP have language access obligations under laws independent of Federal civil rights laws. *See, e.g.*, 42 CFR 435.905(a)–(b)(1) (requiring State agencies administering Medicaid programs to provide language assistance services for applicants and beneficiaries who are limited English proficient); 457.340(a) (requiring State agencies administering CHIP to comply with certain regulatory requirements applicable to Medicaid, including 435.905(a)–(b)(1), which requires that program information be accessible to individuals with LEP); 435.1200(f)(2) (requiring States to make their Medicaid Web sites accessible to individuals with limited English proficiency); 438.10(c)(1)–(5) (specifying obligations for States delivering benefits and services through Medicaid managed care plans, including managed care organizations and certain plans themselves, to make written information available in certain non-English languages, to provide oral interpretation, and to notify individuals with limited English proficiency of the availability of language assistance).

[213] *See, e.g.*, 42 U.S.C. 18031(e)(3)(B) (requiring health plans seeking certification as qualified health plans to provide certain information, including claims payment and rating practices, cost-sharing, and enrollee and participant rights in plain language, which means language that the intended audience, including individuals with limited English proficiency, can readily use and understand); 45 CFR 155.205(c)(2)(i)(A), (ii), (iii)(A), (iv)(B) (requiring telephonic interpreter services, written translation, taglines, and translations of certain Web site content, respectively, for information provided to individuals with limited English proficiency); 156.250 (requiring meaningful access to certain qualified health plan information in accordance with the standards described in 155.205(c)).

In addition, automatically harmonizing requirements imposed on particular entities regulated by both Section 1557 and other laws that the Department enforces would undermine an equally important form of consistency: consistency in enforcement of the standards of Section 1557 and this part across all of the diverse categories of entities covered under the law.

For these reasons and the reasons discussed in the General Comments *supra,* we decline to adopt an approach that automatically deems compliance with CMS or other Federal regulations to be sufficient to demonstrate compliance with Section 1557. However, in circumstances where qualified health plan issuers' compliance with § 92.201 requires steps in addition to those required for compliance with 45 CFR 147.136 or 155.205, OCR will work with qualified health plan issuers to bring them into compliance with § 92.201. In addition, OCR will consider a qualified health plan issuer's compliance with other applicable regulations in determining the appropriate enforcement action.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions in § 92.201 with several modifications.

In § 92.201(a), we replaced the phrase "that it serves or encounters" with "eligible to be served or likely to be encountered."

In § 92.201(b), we implemented a technical revision in paragraph (b)(1) and we modified paragraph (b)(2). With respect to the technical revision in paragraph (b)(1), we modified this proposed phrase: "the nature and importance of the health program or activity, including the particular communication at issue, to the individual with limited English proficiency" by replacing "including" with the conjunction "and." This technical revision clarifies OCR's intent that the particular communication at issue will routinely be a component of the Director's evaluation when the Director gives substantial weight to the nature and importance of the health program or activity. In addition, we modified § 92.201(b)(2) to state that the Director, in evaluating compliance, will take into account all relevant factors, which includes whether a covered entity has developed and implemented an effective written language access plan, appropriate to its circumstances. We eliminated paragraphs (i) through (v) of § 92.201(b)(2).

In § 92.201(d), we broadened the title to reflect that this paragraph now addresses specific requirements for written translation in addition to oral interpretation services. The text in proposed paragraph (d) addressing specific requirements for oral interpretation is now reflected under a new paragraph (d)(1). We added paragraph (d)(2) to require covered entities to use a qualified translator when translating written content in paper or electronic form for its health programs or activities.

In § 92.201(e)(2)(i) and (e)(3), we added "for the individual with limited English proficiency" after "qualified interpreter" to conform to the revision of this term as defined in § 92.4 of the final rule. In addition, we added a new paragraph (e)(4) to address restrictions on a covered entity's use of staff other than qualified bilingual/multilingual staff to communicate directly with individuals with limited English proficiency, in their primary languages.

We re-designated paragraph (f) of § 92.201 in the proposed rule as paragraph (g) of § 92.201 in this final rule, and we added a new paragraph (f). New paragraph (f) provides that when a covered entity uses video remote interpreting services as the means to provide an individual with limited English proficiency oral language assistance, the video remote interpreting technology must meet the standards listed in § 92.201(f)(1)–(4) of this final rule.

Effective Communication for Individuals With Disabilities (§ 92.202)

In § 92.202 of the proposed rule, we proposed to incorporate the provisions governing effective communication with individuals with disabilities found in the regulation implementing Title II of the ADA, which applies to State and local government entities and requires covered entities to ensure that communications with individuals with disabilities are as effective as they are with individuals without disabilities. We noted that OCR typically looks to the ADA for guidance in interpreting Section 504 as the two laws contain very similar standards.

In the proposed rule, OCR considered whether to incorporate the standards in the regulation implementing Title II of the ADA or in the regulation implementing Title III of the ADA, or the standards in both regulations. Standards regarding effective communication under both regulations are very similar. We noted that there are, however, limited differences between the Title II and Title III regulations, regarding limitations on the duty to provide a particular aid or service where doing so may impose undue financial and administrative burdens, and the obligation under the Title II regulation to give primary consideration to the choice of an aid or service requested by the individual with a disability.

OCR proposed to apply the Title II standards to all entities covered under the proposed rule. We noted that although OCR could apply Title II standards to States and local government entities and Title III standards to private entities, we believe it is appropriate to hold all recipients of Federal financial assistance from HHS to the higher Title II standards as a condition of their receipt of that assistance. We also noted that it is appropriate to hold HHS itself to the same standards to which the Department subjects the recipients of its financial assistance.

We also proposed that where the regulatory provisions referenced in § 92.202 use the term "public entity," that term shall be replaced with "covered entity."

The comments and our responses regarding § 92.202 are set forth below.

Comment: A few commenters suggested that HHS urge covered entities to consider the gender preferences of patients for interpreters. These commenters suggested that patients may not be comfortable with interpreters of the opposite gender, particularly in settings that involve nudity such as in an obstetrics and gynecology appointment.

Response: We recognize the commenters' privacy concern, but we decline to accept the commenters' suggestion. We believe that identification with a certain gender specified by the patient is not a characteristic necessary to interpret for an individual with a disability or an individual with limited English proficiency. The definitions of qualified interpreter for an individual with a disability and qualified interpreter for an individual with limited English proficiency set forth in § 92.4 require an interpreter who adheres to generally accepted interpreter ethics, which would include respecting a patient's privacy and comporting oneself with discretion and professionalism in sensitive situations such as the settings described by the commenters. We believe that an interpreter of any gender can display these qualities and thus adequately perform the interpretation duties required of him or her. In those cases where an interpreter is unable to provide interpretation consistent with these standards, the interpreter would be unqualified for those reasons. In addition, acceding to the commenter's request could result in gender discrimination, which contravenes the purpose of other provisions of this rule.

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[214] *See* 45 CFR 155.205(c)(2)(i)(A).

Comment: A few commenters suggested that OCR apply cultural competency standards, such as the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS), to entities serving people with disabilities.

Response: Although OCR does not codify the CLAS standards as part of this regulation, OCR agrees that the CLAS standards provide valuable guidance to covered entities regarding the provision of services that are responsive to diverse cultural beliefs and practices, preferred languages, health literacy and other communication needs, and that promote compliance with the final rule. OCR encourages adoption of the CLAS standards by covered entities for interactions with all their patients and not simply for those with disabilities.

Comment: Some commenters suggested that OCR strengthen effective communication regulations by including the proposed provision regarding the restricted use of certain persons to interpret or facilitate communication contained in § 92.201(e) for individuals with limited English proficiency in § 92.202 for individuals with disabilities.

Response: We appreciate the commenters' suggestion, and note that § 92.202 incorporates provisions of the ADA regarding the restricted use of certain persons to interpret or facilitate communication; it is comparable to the provision in the final rule regarding restrictions on the use of certain persons to interpret or facilitate communication with individuals with limited English proficiency.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, including comments regarding the auxiliary aids and services requirement in § 92.101(b)(2)(i) (discussed above), we are finalizing the provisions proposed in § 92.202 by re-designating the existing regulation text at § 92.202 as § 92.202(a), and adding a new subsection, § 92.202(b) requiring covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

Accessibility Standards for Buildings and Facilities (§ 92.203)

The Section 504 regulatory provisions incorporated into Subpart B in this regulation contain program accessibility requirements that apply to existing facilities as well as new construction and alterations. In § 92.203 of the proposed rule, we proposed to establish specific accessibility standards for new construction and alterations. We noted that these standards are consistent with existing standards under the ADA.

Under paragraph (a), we proposed that each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace^{SM} shall comply with the 2010 ADA Standards for Accessible Design (2010 Standards), as defined in the ADA Title II regulations,[215] if construction or alteration was commenced on or after January 18, 2018. We proposed that all newly constructed or altered buildings or facilities subject to this section shall comply with the requirements for a "public building or facility" as defined in Section 106.5 of the 2010 Standards.

We also proposed that new construction and alterations of such facilities would also be subject to the new construction standards found in the Section 504 implementing regulation at 45 CFR 84.23(a) and (b).

Under paragraph (b), we proposed that each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace^{SM} before January 18, 2018 in conformance with UFAS, the 1991 ADA Standards for Accessible Design (1991 Standards), or the 2010 Standards be deemed to comply with the requirements of this section and with 45 CFR 84.23 (a) and (b), cross referenced in § 92.101(b)(2)(i) with respect to those facilities. Thus, we proposed that if the construction or alteration of facilities began prior to the effective date of paragraph (a) of this section, the facilities be deemed in compliance if they were constructed or altered in conformance with applicable standards at the time of their construction or alteration.

In paragraph (c), we proposed that each building or part of a building that is constructed or altered by or on behalf of, or for the use of, the Department must be designed, constructed, or altered so as to be readily accessible to and usable by individuals with disabilities. We proposed that the definitions, requirements, and standards of the Architectural Barriers Act, as established in Appendices C and D to 36 CFR pt 1191, apply to buildings and facilities covered by this section.

OCR considered adding specific language regarding accessibility standards for medical diagnostic equipment. However, we noted that the United States Access Board is currently developing standards for accessible medical diagnostic equipment and, therefore, we are deferring proposing specific accessibility standards for medical equipment. We further noted that a health program or activity's use of medical diagnostic equipment would be covered by Section 1557 under the general prohibition of discrimination on the basis of disability in § 92.101.

The comments and our responses regarding § 92.203 are set forth below.

Comment: Numerous comments supported requiring immediate compliance with the 2010 ADA Standards for new construction and alterations. Commenters urged that OCR not give covered entities an 18-month grace period for compliance because the 2010 Standards already apply to the vast majority of facilities covered by this proposed rule. They maintained that an approach which emphasizes the uniform application of the 2010 Standards upon publication of the 1557 rule will enable greater consistency among implementing agencies, given the overlapping jurisdiction that OCR has with the Department of Justice.

Response: OCR agrees with the comments in part. Because the great majority of entities covered by the final rule are already subject to the 2010 Standards, the regulation has been revised to require covered entities that were covered by the 2010 Standards prior to the effective date of this final rule to comply with the 2010 Standards for new construction or alterations that commence on or after the effective date of the final rule. However, there may be some entities covered by the final rule that were not covered by the 2010 Standards prior to the effective date of the final rule. For those entities, application of the 2010 Standards would be new; thus, these entities are given 18 months to comply with the final rule with respect to new construction and alterations. We anticipate that these changes will have only a de minimis impact on cost as nearly all of the entities affected are already subject to the 2010 Standards.

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[215] 28 CFR 35.104.

Comment: Numerous commenters recommended that OCR not deem compliance with the UFAS as compliance with Section 1557 for facilities that were constructed or altered prior to 18 months after publication of the final rule. They stated that the UFAS is functionally deficient for people with disabilities; barriers are permitted under the old standard that negatively affect people with mobility and strength disabilities; and, as recognized in the preamble to the proposed rule, nearly all of the facilities covered under the proposed rule are already subject to the 2010 Standards.

Response: OCR appreciates the concern raised by the commenters and agrees with the reasoning underlying the recommendation. OCR has thus modified the language in § 92.203(b) to state that each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace℠ in conformance with the 1991 Standards or the 2010 Standards is deemed to comply with the requirements of the final rule with respect to those facilities, if the construction or alteration was commenced before the effective date of the final rule. Conformance with the UFAS will constitute compliance with the requirements of the final rule only with respect to facilities where construction or alteration was commenced before the effective date of the final rule and only where the facility or part of the facility was not covered by the 1991 Standards or 2010 Standards.

Comment: One commenter recommended that OCR limit the facility accessibility requirements to areas of facilities that actually host consumers (patients of providers, in-person enrollees, etc.) and not apply them to covered entities' facilities more generally. The commenter observed that the ADA standards apply to places of public accommodation, and that if a facility is not public–facing, existing ADA requirements for employees already apply and do not need to be incorporated into this rule. The commenter believed that limiting these requirements to public-facing areas of entities would address consumer needs without creating undue financial and administrative burdens. As an example, the commenter stated that many issuers operate call centers that do not provide face-to-face services to their consumers; therefore, the commenter asserted, it is unclear why the call center would need to comply with physical facility accessibility standards.

Response: OCR notes that applying the building accessibility requirement to facilities or parts of facilities not used in any manner by customers or other program beneficiaries in most cases would be inconsistent with the limited application of the final rule to employment and employees. Thus, this provision is interpreted in light of the limitations on coverage of employment in § 92.101(a) (2); as such, the building accessibility requirement does not apply to facilities or parts of facilities that are visited only by employees of the covered entity except as provided in § 92.208. We believe that this approach is consistent with the ACA's goal of increasing consumer access to health care services and with Section 1557's focus on discrimination against patients, enrollees and other beneficiaries in health programs and activities.

However, we also note that the ADA applies to employment and, in addition, that nearly all of the entities subject to the facility access requirements in the final rule are also subject to facility access requirements under Section 504. Complaints of discrimination related to program accessibility can be brought by employees under the ADA and Section 504, and entities should ensure that they are in compliance with accessibility requirements, including the 2010 Standards, under the ADA.

Comment: Several commenters recommended that OCR require covered entities to make each of their existing facilities accessible to and usable by persons with disabilities. These commenters were concerned that if the accessibility requirement is not applied to each individual facility, then a large for-profit insurance carrier could decide that, among the great majority of its providers who operate in existing facilities, only a small percentage need to be physically accessible or have accessible equipment. Moreover, commenters expressed concern that those accessible providers could be clustered together in some central location, and whenever a member called member services and mentioned the need for accessibility, that member would be actively directed toward the more limited subset of accessible provider offices.

Response: The change urged by the commenter would constitute a new requirement that is inconsistent with existing standards under Title II of the ADA and Section 504, neither of which has been interpreted to require each existing facility to be accessible; rather, they require that the recipient operate each program or activity so that, when viewed in its entirety, it is readily accessible to individuals with disabilities.[216] Thus, we decline to accept the recommendation. We do note that issuers covered by this rule are responsible for ensuring that their health programs provide equal access to individuals without discrimination on the basis of disability. OCR also notes that most providers are recipients of Federal financial assistance from HHS and are themselves independently subject to the nondiscrimination requirements, including program accessibility requirements, in the final rule as well as under Title III of the ADA.

Comment: Some commenters urged that the requirement to comply with accessibility standards be primarily placed on the owners of buildings and facilities, rather than on the providers who rent space. One commenter said that OCR should provide resources and training to small business renters so that they understand what terms in their leases are necessary to ensure that landlords take reasonable responsibility for ensuring their facilities comply with Section 1557.

Response: OCR declines to accept the recommendation to place primary responsibility for compliance with accessibility standards on building owners. Under longstanding legal interpretations of the ADA and Section 504, building owners and lessees each have obligations to refrain from discriminating with respect to program access. OCR also is declining to develop resources and training specifically for small business renters, but notes that the Department of Justice has materials on compliance with accessibility standards under the ADA that may be of use to these entities.[217] In addition, the ADA National Network in HHS supports ten regional centers that provide information, guidance and training on the ADA through services tailored to meet the needs of business, government and individuals at local, regional and national levels.[218] OCR also will develop and make available, before the effective date of the final rule, training materials that cover requirements related to accessibility for individuals with disabilities.

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[216] *See* 28 CFR 35.150(a); 45 CFR 84.22(a); *Bird.* v. *Lewis and Clark Coll,* 303 F.3d 1015, 1021 (9th Cir. 2002), *cert. denied,* 538 U.S. 923 (2003) ("the central inquiry [under the ADA and Section 504] is whether the program, when viewed in its entirety, is readily accessible to and usable by individuals with disabilities").

[217] *See* U.S. Dep't of Justice, ADA Title III Technical Assistance Manual Covering Public Accommodations and Commercial Facilities (1993), § III–1.2000, *http://www.ada.gov/taman3.html.*

Comment: Some commenters urged OCR to exempt entities that are places of public accommodation under Title III of the ADA from the requirements for physical accessibility under Section 1557, stating that additional requirements are confusing and burdensome for small providers. Another commenter recommended that if a health program or activity would not, under Title III of the ADA, be required to be in compliance with a given standard under the 2010 Standards, then the health program or activity should also be exempt from that standard for the purposes of Section 1557 enforcement.

Response: While entities subject to Title III of the ADA include both entities that receive Federal financial assistance and those that do not, the final rule applies only to entities that receive Federal financial assistance, as well as the Department and entities established under Title I of the ACA. We believe it is reasonable to hold entities that receive Federal financial assistance to the accessibility requirements under the final rule, regardless of the standards to which they might be subject under Title III.

Comment: Some commenters said that OCR should require covered entities to make publicly available information on whether medical diagnostic equipment is accessible, so that individuals with disabilities can make informed decisions when choosing a health care provider. A number of commenters recommended that new accessibility standards should be applicable only when physicians upgrade or replace their existing equipment.

Response: As the preamble to the proposed rule noted, standards for accessible medical equipment are in development by the Access Board; thus, OCR is not requiring compliance with specific accessibility standards at this time. In the absence of such standards, covered entities are not in a position to advise or publicize whether their equipment complies with particular standards. Nonetheless, we noted and reiterate here that general accessibility standards that apply to health programs and activities apply to medical equipment, and health service providers must ensure that their health programs and activities offered through the use of medical equipment are accessible to individuals with disabilities.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we have revised § 92.203(a) to state that each covered facility must comply with the 2010 Standards, if the construction or alteration was commenced on or after the effective date of the final rule, except that if a covered facility was not covered by the 2010 Standards prior to the effective date of the final rule, it must comply with the 2010 Standards if the construction was commenced after 18 months after the effective date of the final rule.

For the reasons set forth above and considering the comments received, we have also modified the language in § 92.203(b) to state that each covered facility constructed or altered in conformance with the 1991 Standards or the 2010 Standards will be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction or alteration was commenced before the effective date of the final rule. Further, each covered facility that was constructed or altered in conformance with UFAS will be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction was commenced before the effective date of the final rule and the facility was not covered by the 1991 Standards or 2010 Standards.

Accessibility of Electronic and Information Technology (§ 92.204)

In § 92.204(a), we proposed to require covered entities to ensure that their health programs or activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of an entity's health program or activity.[219] For example, we stated that a Health Insurance Marketplace℠ creating a Web site for application for health insurance coverage must ensure that individuals with disabilities have an equal opportunity to benefit from the Web site's tool that allows comparison of health insurance coverage options, quick determination of eligibility, and facilitation of timely access to health insurance coverage by making its new Web site accessible to individuals who are blind or who have low vision.

We noted that this provision is consistent with existing standards applicable to covered entities. Specifically, Section 508 of the Rehabilitation Act requires that electronic and information technology developed, procured, maintained, or used by Federal agencies be accessible for individuals with disabilities. Section 508 applies to HHS administered health programs or activities, including the Federally-facilitated Marketplaces. Section 504, which applies to recipients of Federal financial assistance, including issuers that receive Federal financial assistance, and Titles II and III of the ADA, which apply to State and local government entities and places of public accommodation, respectively, similarly have been interpreted to require that covered entities' programs, services, and benefits provided through electronic and information technology be accessible to individuals with disabilities.[220] In addition, some States have adopted Section 508 or Web Content Accessibility Guidelines (WCAG) standards for State agency Web sites or electronic and information technology more broadly.

In paragraph (b), we proposed to require State-based Marketplaces and recipients of Federal financial assistance to ensure that their health programs and activities provided through Web sites comply with the accessibility requirements of Title II of the ADA. We noted that our proposed regulatory text cross-references the Title II regulations as a whole, therefore incorporating any future changes to the Title II regulations. We also noted that these requirements are informed by the Department's extensive experience with web-based technology through Federal grant-making programs, including programs that provide funds for State infrastructure changes to allow electronic applications for coverage through the Medicaid program and the Health Insurance Marketplaces, provider adoption of electronic health records, and the development of web-based curricula for health care professionals.

In the proposed rule, we explained that based on the Department's prior experience in this field, we believe that including an explicit, rather than implicit, requirement for electronic and information technology is necessary to clarify the obligations of covered entities to make this technology accessible. In addition, we noted that absent an explicit requirement for accessible electronic and information technology, people with disabilities might not have opportunities to participate in services, programs, and activities that are equal to and as effective as those provided to others, further exacerbating existing health disparities for persons with disabilities.

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[218] For more information or to contact your regional center, please see *https://adata.org/* and *https://adata.org/national-network.*

[219] The terms "undue financial and administrative burdens" and "fundamental alteration" as used in this part have the same meaning that they have under the ADA.

[220] *See, e.g.,* discussion of case law in U.S. Dep't of Justice, Accessibility of Web Information and Services of State and Local Government Entities and Public Accommodations (Advanced Notice of Proposed Rulemaking), 75 FR 43460, 43463-(Jul. 26, 2010).

Given the existing requirements under Section 504, Section 508, and the ADA applicable to information provided through electronic and information technology as a whole, and given the importance of technologies, such as kiosks and applications, to access to health care, health-related insurance and other health-related coverage, we proposed to include an explicit accessibility requirement that applies to all of a covered entity's electronic and information technology, rather than to web access only. We sought comment on this proposal.

We also proposed a general accessibility performance standard for electronic and information technology, rather than a requirement for conformance to a specific set of accessibility standards. We provided that the application of this general accessibility performance standard would be informed by future rulemaking by the Access Board and the Department of Justice. We sought comment on whether the regulation should impose a general accessibility performance standard for electronic and information technology or require that electronic and information technology comply with standards developed pursuant to Section 508 by the Access Board,[221] or the Worldwide Web Consortium's Web Accessibility Initiative's WCAG 2.0 AA.

As noted above, we proposed that covered entities would have a defense to making their health programs and activities provided through electronic and information technology accessible if doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of the health program or activity. In determining whether an action would impose such undue burdens, we proposed that a covered entity must consider all resources available for use in the funding or operation of the health program or activity.

We noted that when undue financial and administrative burdens or a fundamental alteration are determined to exist, the covered entity is still required to provide information in a format other than an accessible electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration, but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology.

The comments and our responses regarding § 92.204 are set forth below.

Comment: A few commenters objected to § 92.204's focus on individuals with disabilities. These commenters noted that Section 1557's nondiscrimination mandate guards against discrimination on the basis of race, color, national origin, sex, and age, as well as disability. Therefore, these commenters recommended that OCR state in § 92.204 that covered entities must ensure that their health programs or activities provided through electronic information and technology are accessible to individuals in all protected classes, not just individuals with disabilities.

Response: Section 92.204 addresses the unique accessibility issues for individuals with disabilities. However, § 92.204's focus on disability does not limit the application of general nondiscrimination principles to the accessibility of health programs and activities offered through electronic and information technology to other groups. Thus, the general prohibition of discrimination set forth in § 92.101(a) requires the accessibility of health programs and activities offered through electronic and information technology, without discrimination on the basis of race, color, national origin, sex, age, or disability.

Comment: One commenter expressed concern that many patients and clients lack internet connectivity in their homes and communities. This commenter stated that while providers should design web-based tools and resources that are user-friendly, appropriate, and effective for patients and clients with disabilities, the providers will need to use alternative creative means to meet the needs of those they serve who lack such connectivity in their homes or communities.

Response: OCR recognizes that many persons lack internet connectivity in their homes and communities and may therefore be unable to access web-based tools and resources provided by covered entities, and encourages entities to develop creative means to meet the needs of these individuals.

Comment: Several commenters asked that OCR clarify the scope of the electronic and information technology requirements. Specifically, these commenters asked OCR whether § 92.204's requirements are limited to the provision of health services.

Response: Section 92.204's requirements are coextensive with, and bounded by, the coverage of Section 1557. Thus, the rule requires covered entities to make all health programs and activities provided through electronic and information technology accessible. Accordingly, this requirement reaches activities such as an online appointment system, electronic billing, and comparison of health plans offered by a Health Insurance Marketplace^{SM}. OCR believes that the regulatory text encompasses this approach.

Comment: A few commenters asked OCR to clarify whether the general requirement under subsection (a) to make health programs and activities that are provided through electronic and information technology accessible applies only to health programs or activities provided through electronic and information technology that are accessed by consumers or also to a covered entity's internal facing electronic information technology. Other commenters urged OCR to limit the application of the general requirement under subsection (a) only to health programs or activities provided through electronic and information technology that are directly related to the activity that made the organization a covered entity and that are accessed by consumers. Conversely, several other commenters recommended that OCR extend the application of subsection (a) to employees of covered entities.

Response: OCR addressed a similar issue in considering facility access requirements above. There, OCR noted that extending the facility accessibility requirement to facilities not used in any manner by customers or other program beneficiaries in most cases would be inconsistent with the limited application of the final rule to employment and employees. Thus, we noted that the facility accessibility requirement is interpreted in light of the limitations on coverage of employment in § 92.101(a)(2).

Similarly, in considering the application of the requirement in the final rule to accessibility of health programs and activities offered through electronic and information technology, we are mindful that the final rule has limited application to employment and employees. In consideration of this limitation, we clarify that the accessibility requirements in the final rule are limited to health programs and activities offered through electronic and information technology that is used by consumers or other program beneficiaries and do not apply to electronic and information technology that is used only by employees of a covered entity and that does not affect or impact customers or program beneficiaries, except as provided in § 92.208.

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[221] 36 CFR pt. 1194.

We also note that the ADA and Section 504 apply to employment, and virtually all of the entities subject to the requirement for accessibility of health programs and activities offered through electronic and information technology in the final rule are also subject to similar general accessibility requirements in the ADA and Section 504. Entities covered by the final rule should be mindful of their obligations under these other laws.

Comment: Some commenters recommended that OCR require different standards for accessibility of electronic and information technology for entities covered under Title II of the ADA, which applies to State and local government entities, and entities covered under Title III of the ADA, which applies to places of public accommodation and commercial facilities.

Response: OCR declines to apply different standards under the final rule. As noted above, State or local government entities that are covered under Section 1557 are already subject to the Title II standards. In addition, the other entities covered under Section 1557 are health programs and activities that either receive Federal financial assistance from HHS or are conducted directly by HHS. Although OCR could apply Title II standards to States and local entities and Title III standards to private entities, we believe it is appropriate to hold all recipients of Federal financial assistance from HHS to the higher Title II standards as a condition of their receipt of that assistance. As a result, OCR declines to impose different standards as recommended by the commenters. This approach is consistent with our approach to § 92.202, in which we are applying Title II standards to all entities covered under Section 1557 with respect to effective communication.

Comment: One commenter asked that OCR exempt places of public accommodation under the ADA from the requirements to make electronic and information technology accessible. Other commenters suggested that the electronic and information technology requirements in the proposed rule are too confusing and burdensome for small providers.

Response: Places of public accommodation covered under the ADA already are required to make health programs and activities offered through electronic and information technology accessible to individuals with disabilities. The ADA does not exempt small providers from this requirement. Thus, the requirements under this final rule should be familiar to entities covered under the ADA.

Comment: Many commenters recommended that OCR require compliance with the accessibility standards set forth in WCAG 2.0, with Level AA as the minimum benchmark. These commenters suggested that compliance with a specific standard would offer clarity to covered entities and consistency to consumers. These commenters also favored WCAG over Section 508 because WCAG is technology agnostic, meaning it is broken down by function rather than product-type, and can apply to future innovations as well as current uses of technology. These commenters also noted that the Access Board is modeling the refreshed Section 508 standards on WCAG 2.0 Level AA, ensuring that HHS's adoption of such a technical standard guarantees that there will be one, universal set of accessibility benchmarks.

Conversely, one commenter stated that OCR should not impose a specific accessibility standard for electronic and information technology, arguing that a specific standard may slow innovation and the establishment of potentially effective electronic information technology alternatives.

Response: OCR has decided not to adopt specific accessibility standards at this time. Nonetheless, we are still requiring covered entities to ensure that health programs and activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of an entity's health program or activity. Thus, when a covered entity chooses to provide a health program or activity through electronic and information technology, the entity must ensure that the technology is accessible as necessary for individuals with disabilities to have equal access to the health program or activity. In our experience, where a covered entity chooses to provide health programs and activities through electronic and information technology, it is difficult to ensure compliance with accessibility requirements without adherence to standards such as the WCAG 2.0 AA standards or the Section 508 standards. Accordingly, OCR strongly encourages covered entities that offer health programs and activities through electronic and information technology to consider such standards as they take steps to ensure that those programs and activities comply with requirements of this regulation and other Federal civil rights laws. Due to the increasing importance of electronic and information technology in health care and health insurance coverage, OCR will continue to closely monitor this area, including developments in the standards developed by the Department of Justice and the Access Board.

Comment: A few commenters asked that OCR give covered entities at least 24 months to come into compliance with the requirements of § 92.204 because they believe there is a significant shortage of available expertise on electronic and information technology. Other commenters recommended that physicians should not be required to comply with new standards until they are ready to upgrade or purchase a new technology product. Still others asked that OCR delay enforcement pertaining to electronic and information technology until health programs and activities can easily select appropriate accessible technology that has been certified by OCR to comply with established standards for accessible technology.

However, many other commenters urged OCR to reject any requests to delay or phase-in the requirements of § 92.204. These commenters pointed out that § 92.204 builds on and reinforces other longstanding accessibility requirements in Federal law; accordingly, it should not be overly burdensome for covered entities to adjust to the requirements of this rule.

Response: OCR is requiring compliance with the requirements of § 92.204 as of the effective date of this regulation. Section 92.204 largely reflects existing standards under the ADA and Section 504, and accordingly, most covered entities are already required to meet § 92.204's standards. Moreover, and with respect to those few covered entities that were not previously subject to the ADA and Section 504 standards, existing undue burden analysis provides adequate safeguards for covered entities that are unable to comply with the requirements of § 92.204 by the effective date.

Comment: One commenter suggested that the responsibility for redesigning health information and technology to improve accessibility should be placed on software vendors and developers rather than on issuers and providers.

Response: The final rule applies to, among other entities, entities that conduct health programs or activities and that receive Federal financial assistance from HHS. Those entities, consistent with longstanding requirements under the ADA and Section 504, must make health programs and activities offered through electronic and information technology accessible to individuals with disabilities. This obligation is not new. Covered entities are not obligated to redesign health information and technology; accessible technology exists and is available to entities covered by the final rule. Thus, HHS is declining to make the change proposed.

Comment: Several commenters suggested that OCR include a reference to specific ADA regulations requiring effective communication in § 92.204.[222] These commenters noted that some of these regulations are the legal origin of the final rule's statement that covered entities must make health programs and activities provided through electronic and information technology accessible. Although these commenters acknowledged that not all of the regulations concerning auxiliary aids and services will apply in the electronic and information technology context, they believe that the explicit incorporation of relevant aspects of these ADA regulations would inform covered entities of other obligations that they might otherwise overlook, such as the obligation to consult and work with individuals with disabilities as part of the entity's effective communication obligation.

Response: OCR believes that intent is clear in the regulation as written. Although OCR is declining to include a reference to 28 CFR 35.160 and succeeding sections in § 92.204, as proposed by the commenters, these sections are incorporated in § 92.202 of the final rule, addressing effective communication with individuals with disabilities. Covered entities are required to comply with both sections of the final rule.

Comment: A few commenters asked OCR to state that electronic information and technology must be functional so that a person with a disability can enjoy all of the same functionality in an equally effective manner and with substantially equivalent ease of use as a user without a disability.

Response: OCR is clarifying here that a covered entity's electronic and information technology must be functional as necessary to ensure that an individual with a disability has equal access to a covered entity's health program and activity. We believe that the regulatory text encompasses this approach.

Comment: Several commenters called attention to problems that persons with disabilities frequently encounter when attempting to access health care. For example, one commenter pointed out that health care service providers' Web sites often include content like videos with audio components. The commenter noted that these videos often lack closed captioning or American Sign Language (ASL) translations that would make the information provided in the video accessible to people with hearing-related disabilities. Accordingly, this commenter suggested that OCR modify § 92.204 to require covered entities to caption or provide ASL translations of audio-based content on their Web sites so that all audio based content is accessible for deaf and hard of hearing individuals.

Another commenter pointed out that, when blind patients seek treatment at a doctor's office, they are often expected to make appointments or fill out required documentation expected of new patients using an inaccessible online portal. In these situations, the blind patient is forced to rely on a third party for assistance and, regardless of their personal relationship, disclose confidential information to that person such as the patient's medical history, illnesses, medications, and history of disease or genetic patterns running in the patient's family. Accordingly, this commenter asked that OCR clarify that covered entities need to make online portals accessible so that blind individuals have the same level of privacy and confidentiality as other individuals.

Response: Under the final rule, covered entities must ensure that the health programs and activities they offer through electronic and information technology are accessible to individuals with disabilities. OCR is not prescribing specific standards for ensuring accessibility and so declines to adopt the commenters' recommendation. However, OCR notes that under § 92.202(a), which incorporates 28 CFR 35.160(b)(2), "[i]n order to be effective, auxiliary aids and services must be provided [to individuals with disabilities] . . . in such a way as to protect the privacy and independence of the individual with a disability." We further remind covered entities to consider the range of accessibility issues that arise for individuals with disabilities and the technology-based solutions that are available to address these issues. The confidentiality of health information is a critical issue, and covered entities must ensure that the private health information of individuals with disabilities is appropriately protected.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.204 without modification.

Requirement To Make Reasonable Modifications (§ 92.205)

In § 92.205, we proposed to require covered entities to make reasonable modifications in policies, practices, or procedures when necessary to avoid discrimination on the basis of disability, unless they can demonstrate that the modification would fundamentally alter the nature of the health program or activity.

We did not receive any significant comments regarding § 92.205. For the reasons set forth in the proposed rule, we are finalizing the provisions proposed in § 92.205 without modification.

Equal Program Access on the Basis of Sex (§ 92.206)

In § 92.206, we proposed that covered entities be required to provide individuals equal access to their health programs or activities without discrimination on the basis of sex and to treat individuals consistent with their gender identity. We proposed that this provision applies to all covered health programs and activities, and prohibits, among other forms of adverse treatment, the discriminatory denial of access to facilities administered by a covered entity. We noted that this proposed approach is consistent with the principle that discrimination on the basis of sex includes discrimination on the basis of gender identity and that failure to treat individuals in accordance with their gender identity may constitute prohibited discrimination.

We proposed one limited exception to the requirement that covered entities treat individuals consistent with their gender identity: That a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one gender based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded in a medical record or by a health insurance plan is different from the one to which such health services are ordinarily or exclusively available. For example, a covered entity may not deny, based on an individual's identification as a transgender male, treatment for ovarian cancer where the treatment is medically indicated.

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[222] Commenters wanted OCR to cite to 28 CFR 35.160(a)(1), (2); 35.160(d); 35.163; and 35.164.

For clarity and consistency within the final rule, we have made some technical revisions to § 92.206. First, regarding a covered entity being prohibited from denying or limiting health services, we are adding the words "to a transgender individual" after "a covered entity shall treat individuals consistent with their gender identity, except that a covered entity may not deny or limit health services, that are ordinarily or exclusively available to individuals of one gender," to clarify that the exception is limited to transgender individuals. We note that similar to the discussion in § 92.207(b)(3), we recognize that not every health service that is typically or exclusively provided to individuals of one sex will be a health service that is appropriately provided to a transgender individual. Nothing in the rule would, for example, require a covered entity to provide a traditional prostate exam to an individual who does not have a prostate, regardless of that individual's gender identity. But for health services that are appropriately provided to an individual, the covered entity must provide coverage for those health services on the same terms regardless of an individual's sex assigned at birth, gender identity, or recorded gender. Second, we are deleting the phrase "in a medical record" to address concerns that "medical records" could be understood as referring only to clinical notes of a health care provider.

The comments and our responses regarding § 92.206 are set forth below:

Comment: A majority of commenters strongly supported the requirement that covered entities provide equal access to health programs and activities without discrimination on the basis of sex and treat individuals consistent with their gender identity. Several commenters noted that discrimination in access to gender-specific facilities remains one of the most common and harmful forms of sex-based discrimination against transgender people, singling them out for humiliation and causing them to avoid the use of such facilities and the associated medical care. Numerous commenters strongly encouraged OCR to strengthen § 92.206 with explicit protections for individuals with non-binary gender identities who need access to gender-specific programs and facilities, and to affirm that individuals with non-binary gender identities should be permitted to determine which facilities are appropriate for them.

Response: OCR recognizes the difficulty that individuals with non-binary gender identities may face in accessing gender-specific programs and facilities. The rule makes clear that in order to meet their obligations under § 92.206, covered entities must treat all individuals consistent with their gender identity, including with regard to access to facilities. OCR has revised the definition of "gender identity" to clarify individuals with non-binary gender identities are protected under the rule from all forms of discrimination based on their gender identity. Thus, OCR does not believe that it is necessary to reiterate protections for non-binary individuals in this context.

Comment: Commenters noted that because pregnant women have experienced considerable discrimination in accessing certain health care services such as mental health care and drug treatment services, the final rule should state that equal access without discrimination on the basis of sex includes equal access without discrimination on the basis of pregnancy.

Response: OCR recognizes the difficulty many pregnant people experience in accessing certain health care services. In response to this concern, OCR is clarifying here that the equal program access provision under § 92.206 is simply a specific application of the more general prohibition of discrimination under § 92.101(a). Under both provisions, denial of program access on any of the prohibited bases, including pregnancy or related medical conditions, is prohibited.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provision as proposed in § 92.206 with technical revisions to clarify our intent and ensure consistency with other parts of the final rule.

Nondiscrimination in Health-Related Insurance and Other Health-Related Coverage (§ 92.207)

In § 92.207 of the proposed rule, we provided specific details regarding the prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability in the provision and administration of health-related insurance or other health-related coverage. We proposed that this prohibition applies to all covered entities that provide or administer health-related insurance or other health-related coverage, including health insurance issuers and group health plans that are recipients of Federal financial assistance and the Department in the administration of its health-related coverage programs. We noted that this section is independent of, but complements, the nondiscrimination provisions that apply to the Health Insurance Marketplaces[223] and to issuers of qualified health plans[224] under other Departmental regulations, and that entities covered under those provisions and Section 1557 are obligated to comply with both sets of requirements.

Based on the longstanding civil rights principles discussed in connection with the definition of "health program or activity" in § 92.4, we proposed to apply this part to all of the coverage and services of issuers that receive Federal financial assistance, whether those issuers' coverage is offered through the Marketplace^{SM}, outside the Marketplace^{SM}, in the individual or group health insurance markets, or as an employee health benefit program through an employer-sponsored group health plan.[225] We provided an example illustrating that an issuer participating in the Marketplace^{SM}, and thereby receiving Federal financial assistance, that also offers plans outside the Marketplace^{SM} would be covered by the regulation for all of its health plans, as well as when it acts as a third party administrator for an employer-sponsored group health plan.[226]

Paragraph (a) proposed a general nondiscrimination requirement, and paragraph (b) provided specific examples of prohibited actions. Paragraphs (b)(1) and (2) proposed to address the prohibition on denying, cancelling, limiting, or refusing to issue or renew a health-related insurance plan or policy or other health-related coverage, denying or limiting coverage of a claim, or imposing additional cost sharing or other limitations or restrictions, on the basis of an enrollee's or prospective enrollee's race, color, national origin, sex, age, or disability, and the use of marketing practices or benefit designs that discriminate on these bases.

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[223] 45 CFR 155.120(c).

[224] 45 CFR 156.200(e); 45 CFR 147.104(e); Public Health Service Act section 2705 (codified at 42 U.S.C. 300gg–4).

[225] Like the proposed rule, the final rule separately addresses employer liability for discrimination in employee health benefit programs at § 92.208.

[226] Where an entity that acts as a third party administrator for an employer's employee health benefit plan is legally separate from an issuer that receives Federal financial assistance for its insurance plans, we proposed to engage in a case-by-case inquiry to evaluate whether that entity is appropriately subject to Section 1557. The final rule addresses this further in the discussions under § 92.2 and § 92.208.

In the proposed rule, we did not propose to require plans to cover any particular benefit or service, but we provided that a covered entity cannot have coverage that operates in a discriminatory manner. For example, the preamble stated that a plan that covers inpatient treatment for eating disorders in men but not women would not be in compliance with the prohibition of discrimination based on sex. Similarly, a plan that covers bariatric surgery in adults but excludes such coverage for adults with particular developmental disabilities would not be in compliance with the prohibition on discrimination based on disability.

In paragraphs (b)(3) through (5) of the proposed rule, we proposed to address discrimination faced by transgender individuals in accessing coverage of health services. We proposed in paragraph (b)(3) that to deny or limit coverage, deny a claim, or impose additional cost sharing or other limitations or restrictions on coverage of any health service is impermissible discrimination when the denial or limitation is due to the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded by the plan or issuer is different from the one to which such services are ordinarily or exclusively available.[227] Under the proposed rule, coverage for medically appropriate health services must be made available on the same terms and conditions under the plan or coverage for all individuals, regardless of sex assigned at birth, gender identity, or recorded gender.

In addition, we noted that many health-related insurance plans or other health-related coverage, including Medicaid programs, currently have explicit exclusions of coverage for all care related to gender dysphoria or associated with gender transition. Historically, covered entities have justified these blanket exclusions by categorizing all transition-related treatment as cosmetic or experimental.[228] However, such across-the-board categorization is now recognized as outdated and not based on current standards of care.[229]

OCR proposed to apply basic nondiscrimination principles in evaluating whether a covered entity's denial of a claim for coverage for transition-related care is the product of discrimination. We noted that based on these principles, an explicit, categorical (or automatic) exclusion or limitation of coverage for all health services related to gender transition is unlawful on its face under paragraph (b)(4); in singling out the entire category of gender transition services, such an exclusion or limitation systematically denies services and treatments for transgender individuals and is prohibited discrimination on the basis of sex.

Moreover, we proposed in § 92.207(b)(5) to bar a covered entity from denying or limiting coverage, or denying a claim for coverage, for specific health services related to gender transition where such a denial or limitation results in discrimination against a transgender individual. In evaluating whether it is discriminatory to deny or limit a request for coverage for a particular service for an individual seeking the service as part of transition-related care, we provided that OCR will start by inquiring whether and to what extent coverage is available when the same service is not related to gender transition. If, for example, an issuer or State Medicaid agency denies a claim for coverage for a hysterectomy that a patient's provider says is medically necessary to treat gender dysphoria, OCR will evaluate the extent of the covered entity's coverage policy for hysterectomies under other circumstances. We noted that OCR will also carefully scrutinize whether the covered entity's explanation for the denial or limitation of coverage for transition-related care is legitimate and not a pretext for discrimination.

We noted that these provisions do not, however, affirmatively require covered entities to cover any particular procedure or treatment for transition-related care; nor do they preclude a covered entity from applying neutral standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner.

We invited comment as to whether the approach of § 92.207(b)(1)–(5) is over- or underinclusive of the types of potentially discriminatory claims denials experienced by transgender individuals in their attempts to access coverage and care, as well as on how nondiscrimination principles apply in this context.

Paragraph (c) of § 92.207 of the proposed rule provided that the enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a) of this section. Paragraph (d) of the proposed rule provided that nothing in § 92.207 is intended to determine, or restrict a covered entity from determining, whether a particular health care service is medically necessary or otherwise meets applicable coverage requirements in any individual case.

The comments and our responses regarding § 92.207 are set forth below.

Comment: Numerous commenters requested clarification regarding the rule's applicability to various health programs or activities that are regulated under other Federal requirements and recommended that OCR deem health programs and activities that comply with existing Federal regulations as in compliance with, or exempt from, Section 1557. For example, commenters requested that compliance with CMS regulations pertaining to qualified health plans or insurance benefit design, such as prescription drug formularies designed by a pharmacy and therapeutics committee,[230] be deemed compliance with the final rule. Numerous commenters also requested that OCR harmonize its language access requirements with existing CMS regulations. This is addressed in the discussion of § 92.201.

In addition, other commenters sought clarification as to the applicability of the rule to wellness programs[231] and value-based insurance designs[232] that are regulated by other Federal departments and agencies, and similarly requested that compliance with other Federal laws regarding these programs be deemed compliance with this final rule. Conversely, regarding employer wellness programs, one commenter wanted OCR to expressly prohibit covered entities from implementing outcomes-based employee wellness programs that base financial rewards or penalties on outcome standards that are coextensive with or directly related to a disability, such as an outcome standard related to high glucose levels, which are directly related to diabetes.

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[227] We note that under § 92.207(a), a covered entity would be barred from denying coverage of any claim (not just sex-specific surgeries) on the basis that the enrollee is a transgender individual.

[228] Liza Khan, *Transgender Health at the Crossroads*, 11 Yale J. Health Pol'y L. & Ethics 375, 393 (2011).

[229] *See infra* note 263. *See also* discussion in the proposed rule at 80 FR at 54189–90.

[230] 45 CFR 156.122(a)(3) (for plan years beginning on or after Jan. 1, 2017).

[231] U.S. Dep't of the Treasury, U.S. Dep't of Labor, and U.S. Dep't of Health & Human Servs., Incentives for Nondiscriminatory Wellness Programs in Group Health Plans (Final Rule), 78 FR 33158 (June 3, 2013).

[232] For a discussion of Value-Based Insurance Design, see Affordable Care Act Implementation FAQs Set 5, Q1, *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html* (last visited May 4, 2016); U.S. Dep't of the Treasury, Dep't of Labor, and U.S. Dep't of Health & Human Servs., Coverage of Certain Preventive Services Under the Affordable Care Act, Final Rule, 80 FR 41318, 41321 (July 1, 2015); and U.S. Dep't of Health & Human Servs., Center for Medicare & Medicaid Servs., Medicare Advantage Value-Based Insurance Design Model (Sept. 1, 2015), *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-09-01.html.*

Response: For the same reasons discussed in connection with the General Comments above,[233] we reject the recommendation to deem health programs or activities that comply with other Federal regulations as automatically in compliance with, or exempt from, the final rule. As a general matter, OCR does not view a covered entity's compliance with other Federal regulations, adopted with different requirements and for different purposes, as determinative of a covered entity's compliance with Section 1557 or other Federal civil rights laws that we enforce. Moreover, deeming compliance in this context must be considered in light of the potential harmful consequences to consumers' health that may occur if covered entities do not adhere to civil rights obligations.

While we reject deeming, OCR will consider a covered entity's compliance with other applicable Federal laws in evaluating a covered entity's compliance with this final rule, and will continue to coordinate with other Federal agencies to promote consistency and avoid duplication in enforcement efforts.

Further, we clarify that evidence-based insurance designs and wellness programs offered through covered entities, such as a health insurance issuer or a group health plan that receives Federal financial assistance, are health programs or activities that are subject to the final rule. We decline to expressly prohibit a particular type of practice by wellness programs in the final rule, as complaints will be reviewed on a case-by-case basis. We note that CMS has made clear that covered entities are responsible for ensuring compliance with other applicable Federal and State laws, including nondiscrimination obligations under Federal laws.[234] We remind covered entities that employer-sponsored wellness programs are considered an employee health benefit program and that employers will be subject to liability for discrimination in such programs under the circumstances identified in § 92.208.

Comment: Several commenters expressed concern that covered entities would not be able to revise their health insurance coverage or other health coverage to comply with the regulation within 60 days after publication, and requested that the effective date of the final rule, in particular § 92.207, be delayed until January 1, 2017 or 2018.[235] These commenters explained that health insurance plans are filed for review with CMS and State insurance regulators during the year before the calendar year in which the plan is offered for sale. Thus, depending on the publication date of the final rule, the commenters suggested that delaying the effective date to plan years (in the individual market, policy years) beginning in 2017 or 2018 would be necessary for issuers to avoid the administrative challenges associated with applying the final rule's requirements in the middle of a plan year or policy year, including amending benefit designs, revising premium rates if applicable, and refiling the products for review with CMS and State insurance regulators. In addition, the commenters noted that issuers are not permitted to adjust rates mid-year for some insurance products.

By contrast, one commenter supported maintaining the proposed effective date, arguing that the benefits of more immediate implementation of the final rule outweigh any expenses or confusion associated with mid-year policy revisions.

Response: We appreciate the concerns expressed by the commenters but we are maintaining the effective date as 60 days after the date of publication of the final rule, except in the limited circumstances described below. Section 1557 has been in effect since its passage as part of the ACA in March 2010, and covered entities have been subject to its requirements since that time. To delay implementation of the final rule would delay the existing and ongoing protections that Section 1557 currently provides and has provided since enactment.[236]

That said, we recognize that some covered entities will have to make changes to their health insurance coverage or other health coverage to bring that coverage into compliance with this final rule. We are sensitive to the difficulties that making changes in the middle of a plan year could pose for some covered entities and are committed to working with covered entities to ensure that they can comply with the final rule without causing excessive disruption for the current plan year.

Consequently, to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

Comment: Several commenters representing issuers and large employers recommended that the rule exempt from Section 1557 benefits that constitute excepted benefits under section 2791(c) of the Public Health Service Act (codified at 42 U.S.C. 300gg–91(c)), which generally are exempt from market reforms under the ACA and HIPAA portability requirements. Excepted benefits include, but are not limited to: limited scope dental and vision plans; coverage only for a specified disease or illness; and Medicare supplemental health insurance (also known as Medigap).[237] Commenters suggested that being excepted from the ACA market reforms and HIPAA portability requirements should result in exemption from Section 1557. Others stated that covering excepted benefits under the rule would serve as a disincentive to employers to provide these benefits due to increased litigation risk.

Response: We are not exempting benefits excepted from ACA market reforms and HIPAA portability requirements from the final rule. If an issuer providing these benefits receives Federal financial assistance and is principally engaged in providing health benefits, all of its operations will be covered by the rule; if it is not principally engaged, we will apply the rule to its federally funded health programs and activities. Many of the benefits excepted from the ACA market reforms and HIPAA portability rules will meet the definition of "health program and activity."[238]

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[233] *See supra* discussion on deeming compliance with other laws in the General Comments section.

[234] 78 FR at 33168; U.S. Dep't of Health & Human Servs., Center for Medicare & Medicaid Servs., Affordable Care Act Implementation FAQs Set 2, Q5, *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html* (last visited May 4, 2016).

[235] The comments addressed in this section pertain to comments related to the implementation date of § 92.207. OCR also received comments requesting a delayed effective date for the rule in general, which are discussed *supra* under § 92.1 of this preamble.

[236] We note that issuers have been provided notice that they are subject to Section 1557 in other Departmental regulations (HHS's Notice of Benefit and Payment Parameters for 2017, Final Rule, 80 FR 12204, 12312 (Mar. 8, 2016); HHS's Notice of Benefit and Payment Parameters for 2017, Proposed Rule, 80 FR 75488, 75553 (Dec. 2, 2015); HHS's Notice of Benefit and Payment Parameters for 2016, Final Rule, 80 FR 10750, 10823 (Feb. 27, 2015)).

[237] 42 U.S.C. 300gg–91(c).

Nothing in the text of Section 1557 limits its coverage only to health programs and activities created or regulated by other provisions of the ACA. Indeed, Section 1557's incorporation of the four civil rights laws to which it refers, as those laws were amended by the CRRA, conclusively suggests otherwise. Moreover, Title VI, Section 504, and the Age Act independently apply to these benefits,[239] and other civil rights laws, such as Title VII, apply to these benefits when they are provided as a fringe benefit of employment by employers covered by that law.

There are several statutorily-defined categories of excepted benefits that are exempt from the ACA market reforms and HIPAA portability requirements if certain conditions are satisfied, such as when medical benefits are incidental or secondary to other insurance benefits, when the benefits are limited in scope or supplemental, or when the benefits are provided as independent, non-coordinated benefits.[240] Excepted benefits do not provide comprehensive medical coverage and do not satisfy the individual or employer responsibility provisions under the ACA. But these characteristics do not justify an exemption from the requirements of Section 1557, which reflects the fundamental policy that entities that operate health programs and activities, any part of which receives Federal funds, cannot use those funds to discriminate—however broad or narrow the scope of those health programs and activities may be.

Comment: Some commenters requested that OCR address a number of issues that are not within the purview of OCR or Section 1557, including the scope of essential health benefit coverage and establishing minimum network adequacy requirements.

Response: OCR appreciates the commenters' suggestions, but the commenters' requests are beyond the scope of this regulation. CMS is statutorily responsible for establishing and regulating the scope of essential health benefits and network adequacy requirements for health insurance issuers. Absent any allegation that a covered entity has discriminated on a basis prohibited by Section 1557, OCR lacks authority to address the terms of these CMS regulations.

Comment: Several commenters asked that OCR exercise more stringent and consistent oversight over consumer access to a wide range of specialists and subspecialists. Commenters pointed out that many qualified health plans in the Marketplace℠ offer network-based plans, and enrollee cost-sharing can be substantially lower when care is delivered by an in-network provider. The commenters expressed concern that some issuers appear to systematically exclude from their provider networks high-cost providers or those in certain high-cost specialties. The commenters suggested that narrow networks could potentially be discriminatory if they deprive patients of reasonable access to a specialty provider or if they discourage enrollment by individuals with specific health needs.

Response: OCR agrees that provider networks with a wide range of specialists and subspecialists are beneficial for consumers and appreciates the concerns expressed about the effect of the exclusion of certain specialists from an issuer's network. We clarify, however, that it is beyond the scope of this regulation to establish uniform or minimum network adequacy standards. Qualified health plan issuers are subject to network adequacy requirements under CMS regulations.[241]

Comment: Some commenters asked OCR to clarify that issuers cannot discriminate against providers based on a provider's protected status. That is, these commenters recommended that OCR make clear that Section 1557's prohibition of discrimination is not limited in scope to the health care consumer and extends to other entities that may be engaged in health programs and activities.

Response: OCR clarifies that covered entities providing or administering health-related insurance or other health-related coverage may not discriminate against or exclude health care providers they contract with on the basis of the provider's race, color, national origin, sex, age, or disability. OCR reminds covered entities that they may have obligations under other Federal laws prohibiting discrimination against providers[242] or against employees.[243]

Comment: A few commenters asked OCR to amend § 92.207(a) so that it more clearly describes the various activities that a covered entity may perform that are considered "administering" health-related insurance or other health-related coverage. Specifically, these commenters asked that OCR add language to § 92.207(a) explaining that administering health-related insurance or other health-related coverage may include claims processing, rental of a provider network, designing plan benefits or policies, drafting plan documents, processing or adjudicating appeals, administering disease management services, and pharmacy benefit management.

Response: We appreciate the commenters' suggestion, but we believe the regulatory text is clear as written and does not require further clarification. The term "administering" is broad enough to encapsulate a variety of activities related to the administration of health-related insurance or other health-related coverage.

Comment: We received a number of comments related to the proper handling of claims alleging discrimination in employee health benefit plans that are covered by both this rule and other Federal laws and regulations. For example, several commenters recommended that the rule not apply to the services of third party administrators providing administrative services to self-insured group health plans. These commenters asserted that Congress did not intend for third party administrators to be covered by Section 1557 and asserted that third party administrators do not design plans, are not responsible for determining the benefits covered under the plan, and are required by ERISA[244] to administer plans as they are written. Commenters also asserted that coverage of third party administrators would indirectly subject self-insured group health plans to Section 1557 and create an unlevel playing field between third party administrators operated by issuers that receive Federal financial assistance and those that do not, thereby creating a disincentive for self-insured group health plans to contract with third party administrators that participate as issuers in the Marketplace℠ and a resulting disincentive for issuers to offer qualified health plans on the Marketplace^{SM}. These commenters also emphasized that self-insured group health plans are already subject to extensive Federal regulation under ERISA.

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[238] We note that non-health-related excepted benefits would be covered under the rule if offered by a covered entity that is principally engaged in providing health care or health coverage.

[239] Title IX applies to these benefits to the extent they are provided in connection with federally funded educational programs or activities.

[240] 42 U.S.C. 300gg–91(c).

[241] 45 CFR 156.230.

[242] *See, e.g.,* 42 U.S.C. 300gg–5(a); 42 CFR 422.205(a).

[243] *See, e.g.,* Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e–2000e–17), the ADA (42 U.S.C. 12101 *et seq.*), the Age Discrimination in Employment Act (29 U.S.C. 621–634); Executive Order 11246 (30 FR 12319, 12935, 3 CFR, 1964–1965, as amended), Section 503 of the Rehabilitation Act of 1973 (29 U.S.C. Sec. 793), and the Vietnam Veterans' Readjustment Assistance Act of 1974 (38 U.S.C. Sec. 4212).

[244] 29 U.S.C. 1001 *et seq.*

Some commenters representing issuers and larger employers also objected to language in footnote 73[245] in the preamble of the proposed rule stating that when an entity that acts as a third party administrator is legally separate from the issuer that receives Federal financial assistance, we will engage in a case-by-case analysis to determine whether the third party administrator is subject to the rule. These commenters stated that the rule should never extend beyond the legal entity that receives the Federal financial assistance.

Response: We are not excluding third party administrator services from the final rule; however, we are adopting specific procedures to govern the processing of complaints against third party administrators.

Third party administrator services are undeniably a health program or activity, as they involve the administration of health services. Under the final rule, if an entity that receives Federal financial assistance is principally engaged in providing or administering health services, health insurance coverage, or other health coverage, then, consistent with the approach taken under the civil rights laws referenced in Section 1557 and under the CRRA, as discussed *supra,*[246] all of its operations are covered. Thus, if an issuer that receives Federal financial assistance is principally engaged in providing health insurance and also provides third party administrator services, there is no principled basis on which to exclude the law's application to the third party administrator services or to treat them differently from other entities and services covered by the rule.

Commenters' assertion that employers or group health plans may have an incentive to contract with third party administrators that are operated by entities that do not receive Federal financial assistance does not justify exempting third party administrator services from the rule. Commenters' rationale would undermine the application of all of the civil rights laws that attach obligations to the receipt of Federal financial assistance; if any competitive disparity exists here, it is no different than in other types of businesses in which some entities receive Federal financial assistance and others do not.

Moreover, the fact that third party administrators are governed by other Federal laws such as ERISA is not a reason to exempt them from Section 1557. ERISA itself explicitly preserves the independent operation of civil rights laws, by providing that nothing in ERISA "shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States . . . or any rule or regulation issued under any such law."[247] And in any event, the fact that entities are subject to regulation under other Federal statutory schemes adopted for other purposes does not justify insulating them from the obligation to comply with civil rights requirements.[248]

Commenters expressed a number of concerns related to the relationship between third party administrators and the employers whose self-insured group health plans they administer. OCR clarifies here that, contrary to the understanding of some commenters, Section 1557's coverage of a third party administrator under the rule does *not* extend to the coverage of an employer providing a group health plan that is being administered by the third party administrator. The rule addresses employer liability separately from that of issuers that receive Federal financial assistance;[249] under Section 1557, an employer is liable for discrimination in its employee health benefit programs only if the employer is principally engaged in health services, health insurance coverage, or other health coverage, or otherwise satisfies one of the criteria set forth in § 92.208. Whether an employer's group health plan is administered by a third party administrator that is a covered entity is not relevant in this analysis.

In response to commenters' arguments on this point, however, OCR recognizes that third party administrators are generally not responsible for the benefit design of the self-insured plans they administer and that ERISA (and likely the contracts into which third party administrators enter with the plan sponsors) requires plans to be administered consistent with their terms.[250] Thus, if a plan has a discriminatory benefit design under Section 1557, a third party administrator could be held responsible for plan features over which it has no control.

Based on these comments, OCR is adjusting the way in which it will process claims that involve alleged discrimination in self-insured group health plans administered by third party administrators that are covered entities. Fundamentally, OCR will determine whether responsibility for the decision or other action alleged to be discriminatory rests with the employer or with the third party administrator. Thus, where the alleged discrimination is related to the administration of the plan by a third party administrator that is a covered entity, OCR will process the complaint against the third party administrator because it is that entity that is responsible for the decision or other action being challenged in the complaint. Where, for example, a third party administrator denies a claim because the individual's last name suggests that she is of a certain national origin or threatens to expose an employee's transgender or disability status to the employee's employer, OCR will proceed against the third party administrator as the decision-making entity. Where, by contrast, the alleged discrimination relates to the benefit design of a self-insured plan—for example, where a plan excludes coverage for all health services related to gender transition—and where OCR has jurisdiction over a claim against an employer under Section 1557 because the employer falls under one of the categories in § 92.208, OCR will typically address the complaint against that employer.

As part of its enforcement authority, OCR may refer matters to other Federal agencies with jurisdiction over the entity. Where, for example, OCR lacks jurisdiction over an employer responsible for benefit design, OCR typically will refer or transfer the matter to the EEOC and allow that agency to address the matter. The EEOC has informed OCR that, provided the filing meets the requirements for an EEOC charge, the date a complaint was filed with OCR will be deemed the date it was filed with the EEOC (although any subsequent denial of a renewed coverage request could be separately challenged by a timely complaint).

This approach is consistent with our efforts to ensure coordination with other Federal agencies that can also exercise jurisdiction over the subject of a particular complaint. Thus, we will also coordinate with the Office of Personnel Management (OPM) in the handling of claims alleging discrimination in the Federal Employees Health Benefits (FEHB) Program. OPM is charged by

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[245] 80 FR at 54189 n.73.

[246] *See supra* discussion of the CRRA under the discussion of "health program or activity" under § 92.4.

[247] 29 U.S.C. 1144(d).

[248] *See supra* discussion on deeming compliance with other laws in the General Comments section.

[249] *See* § 92.208 and discussion of § 92.208 *infra.*

[250] *See* 29 U.S.C. 1104(a)(1)(D).

Federal statute[251] with offering FEHB plans as a fringe benefit of Federal employment and, in that role, approves benefit designs and premium rates, sets rules generally applicable to FEHB carriers, adjudicates and orders payment of disputed health claims, and adjusts policies as necessary to ensure compliance with nondiscrimination standards. As a result, OCR will refer to OPM complaints that allege discrimination in the FEHB Program where OPM is the entity with decision-making authority over the challenged action; OPM will treat these claims as complaints filed against OPM and will seek relief comparable to that available were these claims to be processed by OCR under Section 1557.

In response to the comments requesting additional clarification on footnote 73 in the proposed rule, we reiterate that we will engage in a case-by-case inquiry to evaluate whether a third party administrator is appropriately subject to Section 1557 as a recipient in situations in which the third party administrator is legally separate from an issuer that receives Federal financial assistance for its insurance plans. This analysis will rely on principles developed in longstanding civil rights case law, such as the degree of common ownership and control between the two entities,[252] and will also examine whether the purpose of the legal separation is a subterfuge for discrimination—that is, intended to allow the entity to continue to administer discriminatory health-related insurance or other health-related coverage.[253] But we note that a third party administrator is unlikely to be covered by this final rule where it is a legal entity that is truly independent of an issuer's other, federally funded, activities.

Comment: Commenters requested clarification on OCR's approach when evaluating whether a prohibited discriminatory action occurred under § 92.207(b).

Response: We clarify that OCR's approach in applying basic nondiscrimination principles, as discussed in the proposed rule under § 92.207(b)(5)[254] relating to coverage for specific health services related to gender transition, is the same general approach that OCR will take when evaluating denials or limitations of coverage for other types of health services. In other words, OCR will evaluate whether a covered entity utilized, in a nondiscriminatory manner, a neutral rule or principle when deciding to adopt the design feature or take the challenged action or whether the reason for its coverage decision is a pretext for discrimination. For example, if a plan limits or denies coverage for certain services or treatment for a specific condition, OCR will evaluate whether coverage for the same or a similar service or treatment is available to individuals outside of that protected class or those with different health conditions and will evaluate the reasons for any differences in coverage. Covered entities will be expected to provide a neutral, nondiscriminatory reason for the denial or limitation that is not a pretext for discrimination.

Comment: One commenter asked OCR to clarify that targeted marketing practices designed to reach certain populations to increase enrollment, such as specific segments of those who are uninsured or underserved, are not considered discriminatory. This commenter pointed out that some issuers sometimes launch targeted campaigns to reach a high number of uninsured in their service areas. In so doing, issuers may study the profile of uninsured populations, and based on the results of that study, may concentrate their marketing efforts on certain demographic groups that are disproportionately uninsured or underserved. The commenter cited a Gallup Poll that indicated that roughly one-third of Hispanics remain uninsured, which the commenter stated creates a particular need for issuers to help educate and expand coverage for this community. The commenter sought reassurance that OCR will not consider it discriminatory to target enrollment efforts where they will make the most difference.

Response: Congress intended the ACA to help uninsured and underserved populations gain access to care. Nothing in this regulation is intended to limit targeted outreach efforts to reach underserved racial or ethnic populations or other underserved populations. Indeed, it is OCR's intention that this regulation will increase access for uninsured and underserved populations, much as other Departmental regulations implementing the ACA have strived to do.[255]

Comment: Several commenters recommended that we define "marketing practices" in the regulatory text of § 92.207(b)(2). These commenters suggested that the inclusion of a precise definition for "marketing practices" would serve to clarify the scope of § 92.207(b)(2).

Response: We decline to define "marketing practices" in the final rule because to do so would be overly prescriptive. We emphasize, however, that we intend to interpret the term "marketing practices" broadly; such practices would include, for example, any activity of a covered entity that is designed to encourage individuals to participate or enroll in the covered entity's programs or services or to discourage them from doing so, and activities that steer or attempt to steer individuals towards or away from a particular plan or certain types of plans. We remind covered entities that other Departmental regulations address marketing practices,[256] and covered entities are obligated to comply with all applicable Federal and State laws regarding such practices.

Comment: Many commenters recommended that we define "benefit design" in the regulatory text of the final rule. These commenters suggested that the inclusion of a precise definition of "benefit design" would serve to clarify the scope of § 92.207(b)(2). In addition, numerous commenters requested that we codify or provide examples of benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability. A number of commenters urged OCR to consider specific types of benefit designs as constituting per se discrimination under § 92.207(b)(2) of the final rule.

Response: We appreciate commenters' requests for guidance and clarification regarding potentially discriminatory benefit designs and suggestions for scenarios that constitute per se discrimination. However, we decline to define "benefit design" in the final rule because to do so would be overly prescriptive.[257] We also decline to codify examples of discriminatory benefit designs because determining whether a particular benefit design results in discrimination will be a fact-specific inquiry that OCR will conduct through its enforcement of Section 1557. For the same reason, we avoid characterizing specific benefit design practices as per se discriminatory in the final rule.[258]

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[251] 5 U.S.C. 8901 *et seq.*

[252] *See, e.g., Papa* v. *Katy Indus., Inc.*, 166 F.3d 937, 939 (7th Cir. 1999), *cert. denied*, 528 U.S. 1019 (1999) (ADA, ADEA); *Arrowsmith* v. *Shelbourne, Inc.*, 69 F.3d 1235, 1240–42 (2d Cir. 1995) (Title VII).

[253] *Papa* v. *Katy Indus., Inc.*, 166 F.3d at 941.

[254] 80 FR at 54190.

[255] *See, e.g.*, 45 CFR 155.210(b)(2)(i) (requiring Exchanges to develop and publically disseminate Navigator training standards that ensures expertise in the needs of underserved and vulnerable populations); 81 FR 12204, 12338 (Mar. 8, 2016) (establishing new requirement at 45 CFR 155.210(e)(8) to require Navigators to provide targeted assistance to serve underserved or vulnerable populations).

[256] 45 CFR 156.225(b) (prohibiting qualified health plans from employing marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs); 45 CFR 147.104(e) (prohibiting a health insurance issuer from employing marketing practices or benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, gender identity, sexual orientation, expected length of life, degree of medical dependency, quality of life, or other health conditions); 42 CFR 422.2260–422.2615 (establishing Part D marketing requirements).

OCR will analyze whether a design feature is discriminatory on a case-by-case basis using the framework discussed above. We reiterate that our determination of whether a practice constitutes discrimination will depend on our careful analysis of the facts and circumstances of a given scenario. OCR recognizes that covered entities have discretion in developing benefit designs and determining what specific health services will be covered in their health insurance coverage or other health coverage. The final rule does not prevent covered entities from utilizing reasonable medical management techniques; nor does it require covered entities to cover any particular procedure or treatment. It also does not preclude a covered entity from applying neutral, nondiscriminatory standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner. The rule prohibits a covered entity from employing benefit design or program administration practices that operate in a discriminatory manner.

Comment: We received a number of comments requesting that OCR add language to § 92.207(b) clarifying that categorical exclusions of certain conditions, such as coverage related to developmental disabilities or maternity care, are prohibited.

Response: While categorical exclusions of all coverage related to certain conditions could raise significant compliance concerns under Section 1557, OCR believes that existing regulatory language is sufficient to address this scenario. For example, the law has long recognized that discrimination based on pregnancy is a form of sex discrimination,[259] and OCR has interpreted Section 1557 in the same manner by defining the term "on the basis of sex" in this regulation to include "discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions." As a result, it is unnecessary to add language in response to commenters' concerns.

We note that some products known as excepted benefits, which are subject to this final rule as discussed *supra,* provide limited scope benefits or coverage only for a specified disease or illness.[260] It would not be discriminatory for such products to include exclusions of coverage for conditions that are outside the scope of the benefits provided in those products. Accordingly, the purpose and scope of the coverage provided under health-related insurance or health-related coverage are factors that OCR will consider in determining whether an exclusion of all coverage for a certain condition is discriminatory under this final rule.

Comment: In light of OCR's statement in the preamble to the proposed rule that "[t]he proposed rule does not require plans to cover any particular benefit or service, but a covered entity cannot have a coverage policy that operates in a discriminatory manner," [261] a few commenters asked OCR to clarify that the solution to a potentially discriminatory benefit design could be addition of coverage for a benefit or service.

Response: OCR agrees that the solution to a potentially discriminatory benefit design could be coverage, or added coverage, of a benefit or service.

Comment: The proposed rule invited comment as to whether the approach of § 92.207(b)(1)–(5) is over- or under-inclusive of the types of potentially discriminatory claim denials experienced by transgender individuals in their attempts to access coverage and care, as well as on how nondiscrimination principles apply in this context.[262] Many commenters supported OCR's approach in prohibiting a range of practices that discriminate against transgender individuals by denying or limiting coverage for medically necessary and medically appropriate health services. Numerous commenters asserted that the protections at § 92.207(b)(3)–(5) are vital to ensuring that transgender individuals are able to access the health coverage and care they need and urged OCR to preserve these provisions in the final rule.

For instance, many commenters strongly supported the proposed rule's prohibition against categorical or automatic exclusions of coverage for all health services related to gender transition. These commenters further supported the proposed rule's prohibition against otherwise denying or limiting coverage, or denying a claim, for health services related to gender transition if such a denial or limitation results in discrimination against a transgender individual. These commenters expressed hope that these prohibitions will serve to eliminate the significant barriers that transgender individuals have faced in accessing coverage for transition-related care, such as counseling, hormone therapy, and surgical procedures that they said had previously been denied to them because they have been viewed as cosmetic or experimental. Many commenters also favored the prohibition against denying, limiting, or otherwise restricting coverage for health services that are ordinarily or exclusively available to individuals of one sex based on an individual's gender identity. Commenters indicated that the proposed rule's protections will help to resolve various health care disparities suffered by transgender individuals.

Several commenters, however, opposed the protections that the proposed rule affords to transgender individuals. Some commenters suggested that covered entities should be permitted to categorically exclude coverage for transition-related health services based on moral or religious convictions that an individual's biological sex, or sex assigned at birth, should not be altered. Other commenters suggested that OCR is exceeding its legal authority by addressing covered entities' provision of coverage to transgender individuals because discrimination based on gender identity should not be recognized as a form of sex discrimination.

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[257] We note that "benefit design" is a term of art used in other Departmental and Federal regulations governing the private health insurance industry. *See e.g.,* 42 CFR 422.100(f)(3); 45 CFR 156.225(b); 45 CFR 147.104(e); 29 CFR 2510.3–40(c)(1)(iv)(A).

[258] CMS has identified benefit design features that might be discriminatory. For example, placing most or all prescription medications that are used to treat a specific condition on the highest cost formulary tiers (U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicare Servs., Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters Rule, (Final Rule), 80 FR 10750, 10822 (Feb. 27, 2015); U.S. Dep't of Health & Human Servs., Centers for Medicare and Medicaid Servs., Final 2016 Letter to Issuers in the Federally-facilitated Marketplace, 37 (Feb. 20, 2015)); applying age limits to services that have been found clinically effective at all ages (80 FR at 10822 (Feb. 27, 2015); Final 2016 Letter to Issuers in the Federally-facilitated Marketplace, 36–37 (Feb. 20, 2015)); and requiring prior authorization and/or step therapy for most or all medications in drug classes such as anti-HIV protease inhibitors, and/or immune suppressants regardless of medical evidence (Centers for Medicare and Medicaid Servs., Qualified Health Plan Master Review Tool, Non-Discrimination in Benefit Design (2017), *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Master-Review-Tool_v1-1_03302016.zip* (open "Master Review Tool_2017v1.0.xlsm" document; then open "Non-Discrimination Guidance" tab)).

[259] Title VII prohibits discrimination in employment practices "because of sex," 42 U.S.C. 2000e–2(a), which is defined to include "because of or on the basis of pregnancy, childbirth, or related medical conditions. . . ." 42 U.S.C. 2000e(k); *Newport News Shipbuilding & Dry Dock Co.* v. *EEOC,* 462 U.S. 669, 684 (1983) ("discrimination based on a woman's pregnancy is, on its face, discrimination because of her sex.").

[260] 42 U.S.C. 300gg–91(c).

[261] 80 FR at 54189.

[262] 80 FR at 54191.

Response: We agree with the commenters who expressed their general support of the protections for transgender individuals afforded by the provisions at § 92.207(b)(3)–(5), and therefore we are keeping the provisions as proposed. We believe that it is important to ensure that civil rights protections are extended to transgender individuals to afford them equal access to health coverage, including for health services related to gender transition. As we stated in the preamble to the proposed rule, the across-the-board categorization of all transition-related treatment, for example as experimental, is outdated and not based on current standards of care.[263]

Further, we disagree with commenters who asserted that sex-based discrimination does not include discrimination based on gender identity. As discussed previously,[264] OCR's definition of discrimination "on the basis of sex" is consistent with the well-accepted interpretations of other Federal agencies and courts. Further, as previously noted in this preamble,[265] we decline to adopt a blanket religious exemption in the final rule as any religious concerns are appropriately addressed pursuant to pre-existing laws such as RFRA and provider conscience laws.

Comment: A significant number of commenters recommended that OCR revise the language in § 92.207(b)(4) that prohibits categorical exclusions or limitations of "all health services related to gender transition" to remove the word "all," and proposed modifications to § 92.207(b)(3)–(5) relating to the medical necessity or medical appropriateness of coverage for health services related to gender transition and sex-specific services. Other commenters, concerned that the rule may be too broadly interpreted, requested clarification as to when gender transition services or sex-specific services must be provided and recommended that the rule specify that such health services are to be provided only when medically necessary or medically appropriate. These commenters also requested that OCR clarify that the rule's intent is not to require covered entities to cover elective services or mandate that it cover certain services. Conversely, other commenters specifically requested that the rule clarify that covered entities cannot deny medically necessary services for gender transition-related care because such treatment is medically necessary for transgender individuals. Further, some commenters suggested that covered entities must provide coverage for procedures or services to treat gender dysphoria or associated with gender transition when substantially similar procedures or services are covered for other conditions. For example, commenters observed that a hysterectomy to treat gender dysphoria is substantially similar to a hysterectomy performed for cancer treatment or prevention in a cisgender woman (*i.e.,* a woman whose gender identity is consistent with her sex assigned at birth).

Response: OCR appreciates the array of comments provided but does not believe it is necessary to revise the regulatory text. As noted in the preamble to the proposed rule, we will evaluate whether a particular exclusion is discriminatory based on the application of longstanding nondiscrimination principles to the facts of the particular plan or coverage. Under these principles, issuers are not required to cover all medically necessary services. Moreover, we do not affirmatively require covered entities to cover any particular treatment, as long as the basis for exclusion is evidence-based and nondiscriminatory.

Thus, we reject commenters' suggestion that the rule require covered entities to provide coverage for all medically necessary health services related to gender transition regardless of the scope of their coverage for other conditions.

At the same time, the rule does require that a covered entity apply the same neutral, nondiscriminatory criteria that it uses for other conditions when the coverage determination is related to gender transition. Thus, if a covered entity covers certain types of elective procedures that are beyond those strictly identified as medically necessary or appropriate, it must apply the same standards to its coverage of comparable procedures related to gender transition. As a result, we decline to limit application of the rule by specifying that coverage for the health services addressed in § 92.207(b)(3)–(5) must be provided *only* when the services are medically necessary or medically appropriate.

With regard to § 92.207(b)(3), we recognize that not every health service that is typically or exclusively provided to individuals of one sex will be a health service that is appropriately provided to a transgender individual. Nothing in the rule would, for example, require an issuer to cover a traditional prostate exam for an individual who does not have a prostate, regardless of that individual's gender identity. However, the issuer must cover the health services that are appropriately provided to an individual by applying the same terms and conditions, regardless of an individual's sex assigned at birth, gender identity, or recorded gender.

We also clarify that the prohibition in § 92.207(b)(4) on categorically limiting coverage for all health services related to gender transition is intended to prevent issuers from placing categorical, arbitrary limitations or restrictions on coverage for all gender transition-related services, such as by singling out services related to gender transition for higher co-pays; it is not intended to prevent issuers from placing nondiscriminatory limitations or restrictions on coverage under the plan. We have revised the language of the provision to clarify that intent.

Comment: Some commenters requested that the final rule define "health services related to gender transition."

Response: We decline to include a definition of "health services related to gender transition." OCR intends to interpret these services broadly and recognizes that health services related to gender transition may change as standards of medical care continue to evolve.

The range of transition-related services, which includes treatment for gender dysphoria, is not limited to surgical treatments and may include, but is not limited to, services such as hormone therapy and psychotherapy, which may occur over the lifetime of the individual. We believe the flexibility of the general language in the final rule best serves transgender individuals and covered entities.

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[263] 80 FR at 54189 *See e.g.,* World Professional Association for Transgender Health (WPATH), *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People* (7th ed. 2011), *http://www.wpath.org/uploaded_files/140/files/* Standards Of Care, V7 Full Book.pdf; Institute of Medicine of the National Academies, *The Health of Lesbian, Gay, Bisexual and Transgender People: Building a Foundation for Better Understanding (2011); www.nationalacademies.org/hmd/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx. See also* U.S. Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Division NCD 140.3, Docket No. A–13–87, Decision No. 2576, 22–24 (May 30, 2014), *http://www.hhs.gov/dab/decisions/dabdecisions/dab2576.pdf.*

[264] *See supra* discussion of the definition "on the basis of sex" under § 92.4.

[265] *See supra* discussion on including a religious exemption under § 92.2.

Comment: Several commenters expressed concern that some issuers do not yet have the technological capability to avoid initial denials of coverage for sex-specific services for transgender individuals due to their computer systems flagging a mismatch between the gender of the individual identified at enrollment and the billing code associated with the biological sex that typically receives the health service. The commenters explained that issuers' computer systems accommodate only binary gender billing codes (*e.g.,* "male" or "female") and cannot accommodate descriptions of an enrollee's gender identity. Further, commenters observed that the Health Insurance Marketplace℠ enrollment application available through *HealthCare.gov* permits applicants to identify themselves only as male or female and does not currently allow applicants to denote their gender identity. These commenters noted that, as a result, qualified health plan issuers receive incomplete information about an enrollee's gender identity and biological sex. Moreover, these commenters requested that OCR clarify that an initial denial of a transgender enrollee's claim due to the discrepancy between the enrollee's recorded gender and the sex with which the health service is generally associated does not constitute discrimination if the enrollee is able to reverse the denial through an internal appeals process.

Response: As we indicated in the proposed rule,[266] we recognize that some issuers use computer systems that accommodate only binary gender billing codes that flag a gender mismatch for coverage of certain sex-specific services. We noted that such flagging, by itself, would not be impermissible if it does not result in a delay or denial of services or a claim for services. We reject, however, the commenters' suggestion that an initial denial of a transgender enrollee's claim should never be considered discriminatory as long as the enrollee is able to correct the denial through the internal appeals process. Requiring transgender enrollees to repeatedly go through the internal appeals process to obtain coverage for certain services would subject these enrollees to a burdensome process that is likely to delay their receipt of coverage.

Moreover, there are available interim methods for correcting initial coverage denials due to computer systems flagging a gender mismatch that issuers can use as their computer systems are updated. For instance, we understand that current billing code practices include general billing code modifiers that are used to identify situations in which issuers need to evaluate further claims that might otherwise be automatically rejected. As a result, issuers could advise health care providers to submit an existing billing code modifier along with a claim for sex-specific services for a transgender patient to flag the billing for the issuer's further review.[267] Issuers are free to develop another method of processing claims for sex-specific services by transgender individuals as long as the process is not overly burdensome and provides timely access to care. We note that commenters have raised concerns about the Health Insurance Marketplace℠ enrollment application and will address these concerns as appropriate.

Comment: One commenter recommended that we extend a safe harbor protection to issuers who demonstrate their good faith compliance with § 92.207(b)(3) for the time period during which they update their computer systems and operations to prevent inappropriate denials of coverage for sex-specific services for transgender enrollees.

Response: While we reject the commenter's recommendation of a safe harbor protection, OCR is willing to work with issuers to help identify potential interim solutions and to come into compliance.

Comment: One commenter requested clarification regarding whether an issuer may require transgender enrollees to provide additional information related to their biological sex to enable the issuer to override inappropriate denials of coverage for sex-specific health services. Another commenter inquired as to whether an issuer is permitted to request information about an applicant's biological sex on an insurance application form.

Response: We understand that, in some instances, a covered entity may need to ask transgender enrollees for additional information, including information related to their biological sex or sex assigned at birth, to facilitate overriding denials of coverage for sex-specific health services due to gender billing code mismatches in their computer systems. We clarify in this preamble that a covered entity is permitted to ask transgender enrollees to provide such additional information, as long as the covered entity does not unduly burden enrollees or make unreasonable inquiries that serve to delay their receipt of coverage. In addition, we clarify that it is permissible for a covered entity to request information about the biological sex of the applicant on an insurance application form to assist the covered entity in identifying the medical appropriateness of sex-specific health services, as long as the information requested is not used in a discriminatory manner, and the collection and use of the information is otherwise lawful and complies with applicable HIPAA privacy requirements.

Comment: Many commenters recommended revisions to § 92.207(d), which provides that nothing in this section is intended to determine, or restrict a covered entity from determining, whether a particular health service is medically necessary or otherwise meets applicable coverage requirements in any individual case. Some commenters requested that we revise this provision to ensure that a covered entity does not use criteria that lead to a discriminatory result in its medical necessity or coverage determinations. For example, some commenters suggested that we require covered entities to use certain treatment guidelines when determining medical necessity or coverage for transgender-related health services, such as those published by the WPATH. Conversely, other commenters expressed concern that Section 1557 may unduly restrict a covered entity's ability to evaluate medical necessity in its coverage determinations and requested clarification that covered entities are permitted to require certain treatment, such as mental health services for gender dysphoria, as part of their medical necessity or coverage determinations.

Response: We appreciate the concerns raised by commenters, but we are maintaining the language in § 92.207(d) without revision. OCR will not second-guess a covered entity's neutral nondiscriminatory application of evidence-based criteria used to make medical necessity or coverage determinations. Therefore, we refrain from adding any regulatory text that establishes or limits the criteria that covered entities may utilize when determining whether a health service is medically necessary or otherwise meets applicable coverage requirements. Nevertheless, we caution covered entities that, although § 92.207(d) does not dictate the criteria that a covered entity must use, a covered entity must use a nondiscriminatory process to determine whether a particular health service is medically necessary or otherwise meets applicable coverage requirements.

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[266] 80 FR at 54189 n.75.

[267] The Medicare program already directs providers to use this approach. *See* Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., Medicare Claims Processing Manual, Chapter 32, Transmittal 240: Special Instructions for Certain Claims with a Gender/Procedure Conflict *(last revised Jan. 20, 2015),* (directing providers to use an approved national billing code for sex-specific services for transgender patients to alert the contractor that it is not an error and to allow the claim to continue with normal processing), *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf.*

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.207 with minor technical revisions for clarity, to make our intent clear, and to ensure consistency with other parts of the final rule. We are making technical corrections to paragraphs (b)(1), (b)(3) and (b)(5) to add the word "coverage" where appropriate to reconcile with other parts of the rule. In (b)(1), we are making two modifications to the language. We are reconciling the usage of "health-related insurance" and "other health-related coverage" by adding "related" to those terms in (b)(1). We are also removing reference to "enrollees" as it unintentionally limited application of the paragraph. In (b)(2), we are replacing text that prohibited employing discriminatory marketing practices or benefit designs with text that prohibits having or implementing discriminatory marketing practices or benefit designs to clarify our intent that both having and applying discriminatory marketing practices and benefit design are prohibited. This clarification does not substantively modify the prohibition set forth in the proposed rule. In (b)(3), we are adding the words "to a transgender individual" for clarity, and are deleting the words "by the plan or issuer" for consistency with other parts of the rule. In (b)(4), we are revising the language to be clear that our intent was to prohibit categorical exclusions or limitations in both benefit design and administration; thus, we are replacing language prohibiting categorical or automatic exclusions or limitations of coverage with language that prohibits having or implementing a categorical exclusion or limitation of coverage. This clarification does not substantively modify the prohibition set forth in the proposed rule. In (b)(5), we also are revising the description of the prohibited actions to reconcile the language with other paragraphs in § 92.207(b).

Employer Liability for Discrimination in Employee Health Benefit Programs (§ 92.208)

In § 92.208, we proposed to address the application of Section 1557 to employers that offer health benefit programs to their employees. Under our proposed approach, where an entity that receives Federal financial assistance provides an employee health benefit program to its employees, it will be liable for discrimination in that employee health benefit program under this part only in three defined circumstances.[268] In paragraph (a), we proposed that where an employer is principally engaged in providing or administering health services or health coverage and receives Federal financial assistance, the employer would be subject to Section 1557 in its provision or administration of employee health benefit programs to its employees. Thus, if a hospital provides health benefits to its employees, it will be covered by Section 1557 not only for the services it offers to its patients or other beneficiaries but also for the health benefits it provides to its employees.[269]

In paragraph (b), we proposed that where an entity receives Federal financial assistance the primary objective of which is to fund an employee health benefit program, that entity's provision or administration of the health benefit program will be covered by Section 1557 regardless of the business in which the entity is engaged.

In paragraph (c), we proposed that an employer that is not principally engaged in providing or administering health services or health insurance coverage, but that operates a health program or activity (that is not an employee health benefit program) that receives Federal financial assistance, will be covered for its provision or administration of an employee health benefit program, but only with regard to employees in the health program or activity. Thus, we noted that when a State receives Federal financial assistance for its Medicaid program, the State will be governed by Section 1557 in the provision of employee health benefits for its Medicaid employees, but not for its transportation department employees, assuming no part of the State transportation department operates a health program or activity.

In summary, unless the primary purpose of the Federal financial assistance is to fund employee health benefits, we proposed that Section 1557 would not apply to an employer's provision of employee health benefits where the provision of those benefits is the only health program or activity operated by the employer.

We explained that absent the limitations in § 92.208, employers that receive Federal financial assistance for any purpose could be held liable for discrimination in the employee health benefit programs they provide or administer, even where those employers are not otherwise engaged in a health program or activity and where the use of Federal funds for employee health benefits is merely incidental to the purpose of the assistance. We noted that claims of discrimination in such benefits, brought against employers that do not operate other health programs or activities, could be better addressed under other applicable laws. For example, Title VII of the Civil Rights Act of 1964,[270] the ADA,[271] and the Age Discrimination in Employment Act[272] address claims that an employer has discriminated in the provision of benefits, including health benefits, to its employees.

We proposed to apply the same analysis of employer liability under Section 1557 whether the employee health benefit program is self-insured or fully-insured by the employer. We provided that where an employer that would otherwise be covered under this section creates a separate legal entity to administer its employee health benefit plan, the employer would continue to be liable for the nondiscriminatory provision of employee health benefits to its employees; the employer, as a recipient, may not, through contractual or other arrangements, discriminate on a prohibited basis against its employees.[273]

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[268] As reflected in § 92.101(a)(2) and as discussed in the preamble of the proposed rule, 80 FR at 54180, except as provided here, the proposed rule does not generally apply to discrimination by a covered entity against its own employees. Thus, the rule does not generally extend to hiring, firing, promotions, or terms and conditions of employment outside of those identified in § 92.208; such claims would continue to be brought under other laws, including Title VII, Title IX, Section 504, the ADA and the Age Discrimination in Employment Act, as appropriate.

[269] This approach is consistent with the basic principle underlying the rule and derived from longstanding civil rights interpretations: Where an entity that receives Federal financial assistance is principally engaged in providing or administering health services, health insurance coverage, or other health coverage, all of its operations are covered by Section 1557. *See* discussion *supra* of § 92.2.

[270] 42 U.S.C. 2000e–2000e–17.

[271] 42 U.S.C. 12101 *et seq.*

[272] 29 U.S.C. 621–634.

The comments and our responses regarding § 92.208 are set forth below.

Comment: One commenter expressed the view that while most churches or church boards providing employee health benefits through a church plan would not be covered under § 92.208, some might be covered under § 92.208(c). The commenter expressed the concern that churches that sponsor plans on behalf of numerous employers would not know whether any of those employers operated a health program or activity and received Federal financial assistance and thus would be required to either comply with Section 1557 requirements, even though most or all of the participating employers do not receive Federal financial assistance, or exclude the employer that receives Federal financial assistance from the plan.

Response: The comment reflects a misunderstanding about the application of § 92.208. This section of the regulation applies to employers, not to plan sponsors. In a church plan with multiple participating employers, the plan sponsor will be an entity other than the employer.[274] In this scenario, when an employer is covered under § 92.208(c) and the plan sponsor is a different entity that does not receive Federal financial assistance, it is the employer's obligation, not the plan sponsor's, to ensure that the benefits it provides to employees of its health program or activity do not violate Section 1557. We note that a plan sponsor will be separately covered under Section 1557 if it receives Federal financial assistance and is considered a covered entity under this rule.

Comment: One commenter expressed the view that treating a group health plan as an entity principally engaged in health coverage—and thereby subjecting all of its operations to Section 1557—undermines the limitations on employer liability under § 92.208. The commenter expressed concern that any employer that offers a self-insured group health plan to its employees would be accountable under Section 1557 for any discrimination by that group health plan.

Response: The commenter has misunderstood the relationship between the obligations of an employer and the application of the rule to a separate group health plan providing the employer's employee health benefit program. The fact that a group health plan is principally engaged in providing health services, health insurance coverage, or other health coverage, and therefore must comply with Section 1557 in all of its operations does not necessarily mean that an employer offering an employee health benefit program will be liable for a Section 1557 violation by the group health plan.[275] Employers will be liable under Section 1557 only under the circumstances set forth in 92.208.

Comment: Two commenters requested clarification of whether tax credits claimed by an employer that purchases health insurance coverage through the Small Business Health Options Program (SHOP) Marketplace℠ and the health insurance plan purchased through a SHOP are covered by the rule.

Response: The tax credit to a small employer participating in the SHOP Marketplace℠ is not considered Federal financial assistance from the Department under this rule because the tax credit is not administered by the Department.

Comment: Some comments suggested eliminating or drastically revising § 92.208 to make clear that all covered entities are covered in their provision of employee health benefits. One commenter suggested adding "employee health benefits plan" to the definition of "health program or activity." Another asserted that § 92.208 is unnecessary because all group health plans are health programs or activities. One commenter recommended that OCR include in the regulatory text the substance of footnote 93 from the preamble of the proposed rule,[276] which clarifies that, regardless of whether an employer is liable for a discriminatory employee health benefit plan, an issuer that is a covered entity will be liable for discrimination in the health insurance coverage it offers to employers.

Response: We decline to eliminate or revise § 92.208 in the manner proposed by these commenters. As we explained in the preamble to the proposed rule,[277] absent the limitations in § 92.208, employers that receive Federal financial assistance for any purpose could be held liable for discrimination in the employee health benefits they provide or administer, even where those employers are not otherwise engaged in a health program or activity and where the use of Federal funds for employee health benefits is merely incidental to the purpose of the Federal assistance. We do not believe that Congress intended for Section 1557 to apply in such circumstances. We reiterate that issuers that receive Federal financial assistance and are principally engaged in providing or administering health services, health insurance coverage, or other health coverage are liable for the health insurance coverage offered to employers in connection with a group health plan.

Comment: Some commenters asked us to make clear that employer-provided benefits are covered by the rule even if the employer does not contribute to the cost of these benefits and the entire cost is borne by the employee or other beneficiary.

Response: The rule does not limit employer liability for discrimination in employee health benefit programs to those benefits for which the employer pays for part or all of the cost. Thus, if an employer would otherwise be liable for discrimination in an employee health benefit program, the fact that the employer did not pay for part of the cost of these benefits does not remove it from the reach of 92.208.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.208 with minor technical revisions to ensure consistency with other parts of the final rule by adding the words "or other health coverage."

Nondiscrimination on the Basis of Association (§ 92.209)

In § 92.209 of the proposed rule, we specifically addressed discrimination faced by an individual or an entity on the basis of the race, color, national origin, age, disability, or sex of an individual with whom the individual or entity is known or is believed to have a relationship or association. We explained that the language of Section 1557 makes clear that individuals may not be subject to any form of discrimination "on the grounds prohibited by" Title VI and other civil rights laws; the statute does not restrict that prohibition to discrimination based on the individual's own race, color, national origin, age, disability or sex. Further, we noted that a prohibition on associational discrimination is consistent with longstanding interpretations of existing anti-discrimination laws, whether the basis of discrimination is a characteristic of the harmed individual or an individual who is associated with the harmed individual.[278] A prohibition on associational discrimination is also consistent with the approach taken in the ADA, which includes a specific prohibition of discrimination based on association with an individual with a disability.[279]

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[273] By contrast, with regard to the liability of the legal entity that an employer creates to administer its employee health benefit plan, *i.e.*, a group health plan, we proposed to analyze questions related to the application of Section 1557 on a case-by-case basis consistent with longstanding principles of nondiscrimination law. We will ask, for example, whether the group health plan itself receives Federal financial assistance, such as through receipt of Medicare Part D payments. If it does not, we will evaluate the group health plan's relationship with the employer in assessing whether Section 1557 applies to the group health plan. 80 FR at 54191 n. 94. We noted that a group health plan may be a covered entity under this rule if the group health plan receives Federal financial assistance, as it operates a health program or activity by virtue of its provision or administration of the employee health benefit program. 80 FR at 54191 n. 93.

[274] Under ERISA, when a group health plan is established or maintained by a single employer, the plan sponsor is the employer, but when a group health plan is established or maintained by two or more employers, the plan sponsor is the association, committee, joint board of trustees, or other similar group of representatives of the parties who establishes or maintains the plan. In the case of a plan established or maintained by an employee organization, the plan sponsor is the employee organization. 29 U.S.C. 1002(16)(B).

[275] However, under employment discrimination laws like Title VII, the employer may be liable for the health plan's discrimination. *See, e.g., Los Angeles Dept. of Water and Power* v. *Manhart*, 435 U.S. 702 (1978).

[276] 80 FR at 54191 n. 93.

[277] *Id.*

The comments and our responses regarding § 92.209 are set forth below.

Comment: A few commenters recommended that OCR add the words "or deter" to the prohibition on associational discrimination, so that § 92.209 would read as follows: "A covered entity shall not exclude or deter from participation in, deny the benefits of, or otherwise discriminate against an individual or entity in its health programs or activities on the basis of the race, color, national origin, age, disability, or sex of an individual with whom the individual or entity is known or believed to have a relationship or association."

Response: We believe the regulatory text, as it is currently written, encompasses this approach. It is well established in civil rights law that deterrence is a form of exclusion.[280]

Comment: Several comments recommended that the rule state that unlawful discrimination based on association occurs when a provider is subject to adverse treatment because the provider is known or believed to furnish, refer or support services that are medically appropriate for, ordinarily available to, or otherwise associated with a patient population protected by Section 1557.

Response: To clarify, the rule prohibits covered entities from discriminating against any individual or entity on the basis of a relationship or association with a member of a protected class. The term "individual or entity" includes providers. Thus, for example, an issuer covered by the rule may not use the fact that a provider's clientele is primarily composed of individuals with limited English proficiency to disqualify an otherwise eligible and qualified provider from participation in the issuer's network; such a decision would discriminate against the provider on the basis of the provider's association with a national origin group. We believe that the regulatory text encompasses this approach.

Comment: Commenters asked OCR to clarify whether § 92.209's prohibition of discrimination on the basis of association prohibits discrimination against individuals in same sex relationships.

Response: We will interpret the language of § 92.209 consistent with our interpretation of the term "on the basis of sex," as described in § 92.4 above.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.209 as proposed without modification.

Subpart D—Procedures

Enforcement Mechanisms (§ 92.301)

In proposed § 92.301, we restated the language of Section 1557 regarding enforcement, which provides that the enforcement mechanisms under Title VI, Title IX, the Age Act, or Section 504 apply for violations of Section 1557. We noted that these existing enforcement mechanisms include requiring covered entities to keep records and submit compliance reports to OCR, conducting compliance reviews and complaint investigations, and providing technical assistance and guidance. We further noted that where noncompliance or threatened noncompliance cannot be corrected by informal means, the enforcement mechanisms provided for and available under the civil rights laws referenced in Section 1557 include suspension of, termination of, or refusal to grant or continue Federal financial assistance; referral to the Department of Justice with a recommendation to bring proceedings to enforce any rights of the United States; and any other means authorized by law.[281] In addition, we provided that based on the statutory language, a private right of action and damages for violations of Section 1557 are available to the same extent that such enforcement mechanisms are provided for and available under Title VI, Title IX, Section 504, or the Age Act with respect to recipients of Federal financial assistance. We further provided that a private right of action and damages are available for violations of Section 1557 by Title I entities. We invited comment on these positions.

The comments and our responses regarding § 92.301 are set forth below.

Comment: Many commenters requested that OCR clarify that all enforcement mechanisms available under the statutes listed in Section 1557 are available to each Section 1557 plaintiff, regardless of the plaintiff's protected class. Thus, for example, an individual could bring a race claim under the Age Act procedure and an age claim under the Title VI procedure.

Under this approach, given that the Age Act authorizes a private right of action for disparate impact claims, a private right of action would exist for disparate impact claims of discrimination on the basis of race, color, or national origin.

The commenters primarily rely on reasoning in *Rumble* v. *Fairview Health Services,*[282] in which the U.S. District Court for the District of Minnesota discussed the standards to be applied to Section 1557 private right of action claims and stated: "It appears Congress intended to create a new, health-specific, anti-discrimination cause of action that is subject to a singular standard, regardless of plaintiff's protected class status. Reading Section 1557 otherwise would lead to an illogical result, as different enforcement mechanisms and standards would apply to a Section 1557 plaintiff depending on whether plaintiff's claim is based on her race, sex, age, or disability. For example, it would not make sense for a Section 1557 plaintiff claiming race discrimination to be barred from bringing a claim using a disparate impact theory but then allow a Section 1557 plaintiff alleging disability discrimination to do so."[283]

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[278] *See, e.g., McGinest* v. *GTE Service Corp.,* 360 F. 3d 1103, 1118 (9th Cir. 2004), cert. denied, 552 U.S. 1180 2008) (holding that harassment of white employee who associated with African American employees was discrimination under Title VII); *Tetro* v. *Elliot Popham Pontiac,Oldsmobile, Buick & GMC Trucks Inc.,* 173 F.3d 988, 993–96 (6th Cir. 1999) (holding that white plaintiff with biracial child stated a claim under Title VII based on his own race because Title VII protects victims of discriminatory animus towards third persons with whom one associates); *Parr* v. *Woodmen of the World Life Ins.,* 791 F.2d 888, 892 (11th Cir. 1986)

("Where a plaintiff claims discrimination based upon an interracial marriage or association, he alleges by definition that he has been discriminated against because of his race.")

[279] 42 U.S.C. 12182(b)(1)(E)(Title III); 28 CFR 35.130(g) (Title II). *See generally http:// www.eeoc.gov/facts/association_ada.html. Cf. Loeffler* v. *Staten Island Univ. Hosp.,* 582 F.3d 268, 277 (2d Cir. 2009) (permitting associational discrimination claim under Section 504); *Falls* v. *Prince George's Hosp. Ctr.,* No. Civ. A 97–1545, 1999 WL 33485550 at * 11 (D. Md. Mar. 16, 1999) (holding that parent had an associational discrimination claim under Section 504 when hospital required hearing parent to act as interpreter for child who was deaf). *Cf.* Questions and Answers About the Americans with Disabilities Act's Association Provision.

[280] *See* discussion of § 92.101(a) *supra.*

[281] See 45 CFR 80.8(a).

[282] No. 14–CV–2037 2015 WL 1197415 (D. Minn. Mar. 16, 2015).

Similarly, many commenters requested that the regulation clarify that a private right of action exists for disparate impact claims, arguing, like commenters discussed above, that all enforcement mechanisms should be available to all Section 1557 complainants. A few commenters requested that the availability of a private right of action be addressed in the final rule itself, rather than in the preamble.

Response: OCR interprets Section 1557 as authorizing a private right of action for claims of disparate impact discrimination on the basis of any of the criteria enumerated in the legislation. At the same time, OCR is incorporating its existing procedures for its administrative processing of complaints; thus, we will use our current processes to address age discrimination on the one hand and race, color, national origin, sex, or disability on the other hand. This approach will enable us to be consistent in our processing of complaints under OCR's other authorities in instances where we have concurrent jurisdiction under Section 1557 and the other civil rights laws it references. This approach is not intended to limit the availability of judicial enforcement mechanisms. We note as well that both the proposed and the final rule specify that a private right of action is available under Section 1557.

Comment: A few commenters suggested that the text of the regulation specifically mention the availability of compensatory damages. Although OCR discussed the availability of compensatory damages in the preamble of the NPRM, commenters recommended that explicit authorization for compensatory damages in the regulation would strengthen the enforcement of Section 1557.

Response: OCR has added a provision to § 92.301 to make clear in the regulation that compensatory damages are available. Our interpretation of Section 1557 as authorizing compensatory damages is consistent with our interpretations of Title VI, Section 504, and Title IX.

Comment: Many commenters requested that OCR involve the Department of Justice (DOJ) in all Section 1557 investigations and compliance reviews where DOJ has concurrent jurisdiction, and that OCR refer cases to DOJ for litigation, where appropriate.

Response: Although OCR recognizes the importance of working with DOJ and other agencies, it would not be a productive use of resources to include DOJ in every case in which it has concurrent jurisdiction. OCR has been enforcing Section 1557 since it became effective in 2010 and continues to investigate and resolve Section 1557 cases over which it has jurisdiction. OCR involves DOJ in investigations where appropriate and will continue to do so. And, as § 92.209 makes clear, OCR has the authority to refer cases to DOJ for litigation where efforts at compliance have been unsuccessful.

Comment: Some commenters recommended that HHS agreements with State agencies and State contracts with Medicaid managed care organizations include nondiscrimination provisions that obligate the State agencies to ensure compliance with nondiscrimination requirements.

Response: OCR agrees that nondiscrimination provisions in contracts help covered entities to ensure that contractors do not discriminate against program beneficiaries. Although this rule does not require such provisions in contracts, OCR has worked with HHS entities to include such language in their contracts in the past, and OCR will continue to look for opportunities to promote compliance with civil rights laws through nondiscrimination provisions in contracting in the future.

Comment: Several commenters recommended that the regulatory text specifically provide that OCR will conduct compliance reviews and perform outreach. These commenters expressed concern that individual complaint resolution, as an enforcement mechanism, will be inadequate to achieve widespread compliance with the Section 1557 final rule.

Response: We recognize the need for OCR to employ the full range of enforcement tools in order to ensure compliance with the law, and we intend to continue in our robust enforcement of Section 1557. We do not believe that any changes to regulatory text are necessary, since the rule contemplates and authorizes the suite of enforcement mechanisms that OCR has long employed.

Comment: Some commenters recommended that HHS, and not States, should be the primary enforcement agency for benefit design issues. These commenters asserted that State enforcement would lead to inconsistent results.

Response: OCR is responsible for enforcement with respect to benefit design issues under Section 1557. States have an important role in ensuring compliance with nondiscrimination requirements respecting insurance, including benefit design, under CMS regulations and applicable State laws. It is beyond the scope of this rulemaking to change State obligations under those laws.

Comment: Some commenters recommended that OCR be required to publish the outcomes of all resolved Section 1557 complaints and statistics regarding Section 1557 complaints received by OCR.

Response: We decline to accept this recommendation, but OCR will continue to include information and corrective action plans and resolution agreements on the OCR Web site.

Comment: Some commenters recommended that OCR allow at least a one-year period with no administrative sanctions if a covered entity can demonstrate good faith compliance. These commenters suggested that this approach will promote compliance while covered entities, OCR, and consumers become familiar with the requirements of the regulation.

Response: We appreciate the commenters' recommendation, but we decline to accept it because, while good faith is relevant under certain CMS regulations with which covered entities may be familiar, courts have not treated good faith as a consideration in assessing whether a covered entity is in compliance with the civil rights laws referenced in Section 1557. We are retaining this principle in interpreting whether a covered entity is in compliance with Section 1557. That said, OCR has the authority and discretion to consider a range of factors when reviewing cases and determining appropriate remedies, including consideration of steps taken by covered entities to ensure compliance with the law, compliance with other Federal regulations regarding the issue, timeframes for implementation of corrective action and resources to facilitate compliance.

Comment: Some commenters suggested that the final rule mandate training for employees of entities required to comply with the requirements of Section 1557.

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[283] *Id.* at *11.

Response: Although OCR encourages covered entities to train employees on compliance with Section 1557 periodically, OCR does not believe it is necessary for the final rule to mandate training. However, to facilitate training that covered entities choose to provide, we are preparing and will make available a training curriculum for their use in advance of the effective date of the rule. We also expect to engage in outreach and technical assistance to promote understanding of and compliance with the final rule.

Comment: Several commenters stated that the final rule should require OCR to perform unannounced, onsite reviews of covered entities to ensure compliance with Section 1557.

Response: While OCR may consider performing unannounced, onsite reviews where appropriate, OCR does not believe it is necessary to include a requirement to do so in the final rule.

Comment: Some commenters recommended that the regulation permit class actions and third party complaints in court. Other commenters recommended that the regulation provide for the availability of attorneys' fees in successful private suits. These commenters pointed out that many individuals who are subject to discrimination will be unable to afford a retainer for an attorney. Some commenters recommended that suits be allowed only in the State where the Marketplace^{SM} is located, not any Federal district court in a district in which a complainant resides.

Response: Although these issues are outside the scope of this regulation, nothing in Section 1557 changes the laws that otherwise would govern eligibility for attorneys' fees, including the Civil Rights Attorney's Fees Award Act of 1976,[284] laws that otherwise would govern venue,[285] or laws that otherwise would govern initiation of class action lawsuits.[286]

Comment: Some commenters suggested that the regulation prohibit issuers from including clauses requiring mandatory binding arbitration of Section 1557 complaints. These commenters asserted that such arbitration is unfair to consumers.

Response: We decline to accept the commenters' suggestion because it is outside the scope of this regulation.

Summary of Regulatory Changes

For the reasons set forth above and in the proposed rule and considering the comments received, we have revised § 92.301 to re-designate existing text as § 92.301(a) and add a new subsection (b) stating that compensatory damages for violations of Section 1557 are available in administrative and judicial actions, as they are under authorities referenced in Section 1557.

Procedures for Health Programs and Activities Conducted by Recipients and State-Based Marketplaces (§ 92.302)

In § 92.302, we proposed the procedures that will apply to enforcement of Section 1557 in health programs and activities conducted by recipients and State-based Marketplaces. We noted that the administrative procedures provided for and available under Title VI are found in the regulation implementing Title VI.[287] We explained that these administrative procedures are incorporated into the regulation implementing Title IX[288] and Section 504 with respect to recipients.[289] In paragraph (a), we proposed to incorporate these procedures into Section 1557 with respect to race, color, national origin, sex, and disability discrimination.

We also explained that the administrative procedures provided for and available under the Age Act are found in the regulation implementing the Age Act.[290] In paragraph (b), we proposed to incorporate these procedures into Section 1557 with respect to age discrimination.

In paragraph (c), we provided that an individual may bring a civil action in a United States District Court in which a recipient or State-based Marketplace^{SM} is located or does business, as provided for and available under Section 1557.

The comments and our responses regarding § 92.302 are set forth below.

Comment: A few commenters asserted that any enforcement provisions that apply to Health Insurance Marketplaces should apply whether the Marketplace^{SM} is operated by the State or Federal government.

Response: OCR declines to incorporate the commenter's request that Marketplaces operated by the Federal government be subject to the same enforcement provisions as Marketplaces operated by State governments. Under the regulations implementing Section 504, federally assisted programs, including federally assisted programs operated by States, and federally conducted programs are subject to separate enforcement procedures.[291] OCR believes that this approach has worked successfully in the past and has decided to retain separate procedures for federally conducted health programs and activities, including Health Insurance Marketplaces operated by HHS, and other health programs and activities, including Health Insurance Marketplaces operated by States.

Comment: Some commenters suggested that OCR use the enforcement scheme of Title VI for all discrimination under Section 1557. By contrast, some commenters recommended that the final rule should require mediation for all Section 1557 complaints. A few commenters requested that OCR require exhaustion of administrative remedies before individuals could pursue a private right of action.

Response: OCR declines to adopt these recommendations. OCR has decided to retain administrative procedures and application of the procedures consistent with OCR's existing procedures for complaints. Mediation and exhaustion of administrative remedies will still be required for age discrimination allegations in complaints, but not for allegations of other covered types of discrimination.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.302 with two modifications. As addressed previously in the discussion of the comments on § 92.5 (Assurances), the text that was previously found at § 92.302(c) has been moved to § 92.302(d), and § 92.302(c) now clarifies OCR's ability to initiate enforcement procedures where a recipient or State-based Marketplace ^{SM} fails to provide OCR with requested information.

Procedures for Health Programs and Activities Administered by the Department (§ 92.303)

In the proposed rule, we noted that Section 1557 expressly states that the enforcement mechanisms provided for and available under Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of violations of Section 1557. We also noted that the administrative procedures provided for and available under Section 504—the only one of these statutes that applies to federally conducted, as well as federally assisted, programs—for programs and activities administered by the

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[284] 42 U.S.C. 1988.

[285] *See, e.g.,* 28 U.S.C. 1391.

[286] *See, e.g.,* 28 U.S.C. 1332.

[287] 45 CFR 80.6–.11; 45 CFR pt. 81.

[288] 45 CFR 86.71.

[289] 45 CFR 84.61.

[290] 45 CFR 91.41–.50.

[291] *Compare* 45 CFR 84.61 *with* 45 CFR 85.61–.62.

Department are found in the regulation implementing Section 504.[292] We provided that these procedures shall apply with respect to complaints and compliance reviews of health programs or activities administered by the Department, including the Federally-facilitated Marketplaces, concerning discrimination on the basis of race, color, national origin, sex, age, or disability.

In the proposed rule, we proposed to add two provisions that are not found in Section 504 enforcement procedures for programs conducted by the Department. We proposed that the first provision, which reflects OCR's practice under Section 504 and mirrors similar requirements under the Title VI regulation with regard to access to information, is designed to ensure that OCR has the ability to obtain all of the relevant information needed to investigate a complaint or determine compliance in a particular health program or activity administered by the Department.

We further proposed language prohibiting the Department, including Federally-facilitated Marketplaces, from retaliating against any individual for the purpose of interfering with any right or privilege under Section 1557 or the proposed rule or because the individual has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under Section 1557 or this proposed rule. We explained that Section 504 of the Rehabilitation Act, to which the Department is already subject, provides that the procedures, rights, and remedies under Title VI are available to any individual aggrieved by an act or failure to act by any recipient of Federal financial assistance or Federal provider of such financial assistance under Section 504. Thus, we noted that the prohibition on retaliation under Title VI[293] would apply to the Department under Section 504. We noted that the retaliation provision in the proposed rule is simply an extension of this existing prohibition. We further noted that this provision is also in accordance with a similar requirement for recipients under the Title VI regulations. The Department should hold itself to the same standards to which it holds recipients of Federal financial assistance.[294]

Summary of Regulatory Changes

We did not receive any significant comments regarding § 92.303. For the reasons set forth in the proposed rule, we are finalizing the provisions proposed in § 92.303 without modification.

Information Collection Requirements

The notice of proposed rulemaking called for new collections of information under the Paperwork Reduction Act of 1995.[295] As defined in implementing regulations,[296] "collection of information" comprises reporting, recordkeeping, monitoring, posting, labeling and other similar actions. In this section, we first identify and describe the entities that must collect the information, and then we provide an estimate of the total annual burden. The estimate covers the employees' time for reviewing and posting the collections required.

The final rule calls for the same collections of information as the notice of proposed rulemaking, with one addition: The cost estimates for covered entities to develop and implement a language access plan, should the covered entities choose to do so, given that development and implementation of a language access plan is one of the factors that the Director will consider, if relevant, in assessing whether a covered entity has met its obligation to take reasonable steps to provide meaningful access to each individual with limited English proficiency.

Title: Nondiscrimination in Health Programs and Activities.

OMB Control Number: XXXX–XXXX.

Summary of the Collection of Information: The final rule estimates four categories of information collection: (1) Submission of an assurance of compliance form, per § 92.5; (2) posting of a nondiscrimination notice and posting of taglines, under § 92.8; (3) development and implementation of a language access plan, anticipated per § 92.201; and (4) designation of a compliance coordinator and adoption of grievance procedures for covered entities with 15 or more employees, per § 92.7. Each category is described in the following analysis.

Under the final rule, each entity applying for Federal financial assistance, each health insurance issuer seeking certification to participate in a Marketplace℠, and each entity seeking approval to operate a Title I entity is required to submit an assurance that its health programs and activities will be operated in compliance with Section 1557.

In addition, each covered entity subject to the final rule is required to post a notice of individuals' civil rights and covered entities' obligations, including acknowledging that the covered entity provides auxiliary aids and services, free of charge, in a timely manner, to individuals with disabilities, when such aids and services are necessary to provide an individual with a disability an equal opportunity to benefit from the entity's health programs or activities; and language assistance services, free of charge, in a timely manner, to individuals with limited English proficiency, when those services are necessary to provide an individual with limited English proficiency meaningful access to a covered entity's health programs or activities. Furthermore, each covered entity is required to post taglines in the top 15 languages spoken by individuals with limited English proficiency by relevant State or States, informing individuals with limited English proficiency that language assistance services are available.

Although the final rule does not require covered entities to develop a language access plan, the development and implementation of a language access plan is one factor that the Director will consider when evaluating a covered entity's compliance with this rule. We anticipate that some proportion of covered entities will develop and implement a language access plan following issuance of the rule.

Additionally, each covered entity that employs 15 or more persons is required to adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557. Each covered entity is also required to designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557, including the investigation of any grievance communicated to it alleging noncompliance with Section 1557.

Need for Information: The requirement that every entity applying for Federal financial assistance, seeking certification to participate in a Health Insurance Marketplace℠, or seeking approval to operate a Title I entity, submit an assurance of compliance, is similar to the current regulatory requirements under Title VI,[297] Section 504,[298] and the Age Act.[299] These requirements protect individuals by assuring that covered entities will comply with all applicable nondiscrimination statutes and their implementing regulations.

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[292] 45 CFR 85.61–.62.

[293] 45 CFR 80.7(e).

[294] Further, as the U.S. Supreme Court observed in *Jackson* v. *Birmingham Bd. of Educ.*, 544 U.S. 167, 180 (2005), protecting individuals from discrimination under Title IX "would be difficult, if not impossible, to achieve if persons who complain about sex discrimination did not have effective protection against retaliation." (citing to the brief of the United States as Amicus Curiae). The same principle is true for discrimination under Section 1557.

[295] 44 U.S.C. 3501–3520.

[296] 5 CFR 1320.3(c).

The posting of a notice of individuals' rights and covered entities' obligations and the posting of taglines in the top 15 languages spoken by individuals with limited English proficiency by relevant State or States are necessary to ensure that individuals are aware of their protections under the law, and are grounded in OCR's experience that failures of communication based on the absence of auxiliary aids and services and language assistance services raise particularly significant compliance concerns under Section 1557, as well as Section 504 and Title VI.

The development and implementation of a language access plan helps ensure meaningful access to persons with limited English proficiency to a covered entity's health programs and activities. While Title VI has long required covered entities to take reasonable steps to provide persons with limited English proficiency meaningful access, the addition of a language access plan brings specificity and increased probability of implementation of the requirement. Although the final rule does not require development and implementation of a language access plan, covered entities may choose to develop and implement a language access plan because the Director will consider, if relevant, the language access plan as one factor when assessing a covered entity's compliance with this rule.

The requirements that every covered entity that employs 15 or more persons adopt grievance procedures and designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557 are similar to requirements included in the Title IX and Section 504 implementing regulations. Through its case investigation experience, OCR has observed that the presence of a coordinator and grievance procedures helps to bring concerns to prompt resolution within an entity, leading to lower compliance costs and more efficient outcomes.

Use of Information: OCR will use this information to ensure covered entities' adherence to the statutory requirements imposed under Section 1557 and this final rule. OCR will enforce the requirements by verifying during investigations of covered entities that an entity has submitted an assurance of compliance and posted the notice and taglines and, for each covered entity that employs 15 or more persons, that an individual has been designated to coordinate its compliance efforts and that appropriate grievance procedures have been adopted, as required.

Description of the Respondents: The respondents are: the Department, each entity that operates a health program or activity, any part of which receives Federal financial assistance, and each entity established under Title I of the ACA that administers a health program or activity. These include such entities as hospitals, home health agencies, community mental health centers, skilled nursing facilities, and health insurance issuers.

Number of Respondents: The number of respondents is estimated to include the 275,002 covered entities affected by the final rule.

Burden of Response: Because the Department provides the assurance of compliance and the final rule provides a sample Notice, sample taglines in 64 languages, and sample grievance procedures, the burden on respondents is minimal. Additionally, because all recipients of Federal financial assistance with 15 or more employees are already expected under other laws to have in place grievance procedures and a designated individual to coordinate their compliance responsibilities, the burden to comply with this requirement will be minimal for most respondents.

The requirement to sign and submit an assurance of compliance exists under other civil rights regulations (Title VI, Section 504, Title IX, the Age Act), and since the Department provides a copy of the Assurance of Compliance form to covered entities, OCR believes this requirement adds no extra burden. OCR believes that the time, effort, and financial resources necessary to comply with this requirement are considered part of the usual and customary business practice and would be incurred by covered entities during their ordinary course of business.

OCR estimates that the burden for responding to the proposed notice requirement is an average of 17 minutes to download and post the notice and that the burden to download and post taglines in the top 15 languages by relevant State or States is also an average of 17 minutes, for a burden total of 34 minutes on average at each of the 405,534 affected establishments (associated with the affected covered entities) in the first year following publication of the final rule. (See Regulatory Impact Analysis, II. Costs, B.2.for a more detailed explanation of the differences between "firm" and "establishment.") We estimate that administrative or clerical support personnel would perform these functions. Based on the wage rate for a Clerical Support Worker ($15.52) we estimate the annual burden for these two requirements to be approximately $7.1 million after adjusting for overhead and benefits by adjusting the wage rate upward by 100%.

OCR estimates that the burden for developing a language access plan is approximately three hours of medical and health service manager staff time in the first year, and an average of one hour of medical and health service manager staff time per year to update the plan in subsequent years. The value of an hour of time for people in this occupation category, after adjusting for overhead and benefits, is estimated to be $89.24 based on Bureau of Labor Statistics (BLS) data. As discussed later in this analysis, we estimate that approximately 135,000 entities will develop and implement language access plans, as part of the requirement to take reasonable steps to provide meaningful communication with persons with limited English proficiency. These assumptions imply that the total cost of the development of language access plans will be approximately $36.0 million (269,141 entities × 50% of entities × 3 hours per entity × $89.24 per hour) in the first year and approximately $12.0 million (269,141 entities × 50% of entities × 1 hour per entity × $89.24 per hour) per year in subsequent years.

Regarding the requirement that every covered entity that employs 15 or more persons adopt grievance procedures and designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557, based on OCR's complaint workload increase since the enactment of Section 1557, we anticipate that within the first five years following the rule's enactment, complaints will increase approximately 0.5% in the first year, 0.75% in the second year, and 1% in years three through five, but eventually will drop off as covered entities modify their policies and practices in response to this final rule. We estimate that medical and health service managers will handle the grievances, and that a 1% increase in complaints will require 1% of an FTE at each covered entity. Using the annual wage rate for medical and health service managers ($103,680), adjusting for fringe benefits and overhead, and multiplying by the 41,250 entities affected by this requirement, we estimate the annual burden for this requirement to be approximately $42.8 million in year one, $64.2 million in year two, and $85.5 million for each year in years three, four, and five following publication.

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[297] 45 CFR 80.4(a).

[298] 45 CFR 80.5.

[299] 45 CFR 91.33.

Thus, the total estimated annual burden cost for the proposed information collection requirements will be approximately $86.0 million in the first year, $76.2 million in the second year, and $97.5 million per year in years three through five following publication of the final rule.

We asked for public comment on the proposed information collection to help us determine:

1. Whether the proposed collection of information is necessary for the proper performance of the functions of OCR, including whether the information will have practical utility;
2. The accuracy of the estimated burden associated with the proposed collection of information;
3. How the quality, utility, and clarity of the information to be collected may be enhanced; and
4. How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology.

We received no comments with specific data in response to numbers one, two, or three above. With regard to question four, we received comments asking that the proposed collection of information be minimized and stating that it is burdensome for covered entities to develop notices to put in several locations in all their facilities. OCR responded by proposing that OCR develop a model notice of important information and model taglines, to minimize the burden on covered entities. The new cost analysis is included above, in this Information Collection section, as well as in the Regulatory Impact Analysis.

Regulatory Impact Analysis

I. Introduction

A. Executive Orders 12866 and 13563

Executive Order 12866 [300] directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 [301] is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. OMB has determined that this final rule is a "significant regulatory action" under Executive Order 12866. Accordingly, OMB reviewed this final rule.

In general, we received few comments with regard to the Regulatory Impact Analysis (RIA), and thus the analysis in the final rule remains fairly similar to the proposed rule, although there are some changes. The comments will be addressed in each section below, as appropriate.

B. The Need for a Regulation

Section 1557 of the ACA prohibits an individual from being excluded from participation in, denied the benefits of, or otherwise subjected to discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities. It applies to any health program or activity, any part of which is receiving Federal financial assistance, and to any program or activity that is administered by an Executive Agency or any entity established under Title I of the ACA.[302] The Secretary of the Department is authorized to promulgate regulations to implement Section 1557 under the statute and 5 U.S.C. 301. The purpose of this regulatory action is to implement Section 1557 of the ACA.[303]

One of the central aims of the ACA is to expand access to health care and health coverage for all individuals. Equal access for all individuals without discrimination is essential to achieving this goal. Discrimination in the health care context can often lead to poor and inadequate health care or health insurance or other coverage for individuals and exacerbate existing health disparities in underserved communities. Individuals who have experienced discrimination in the health care context often postpone or do not seek needed health care; individuals who are subject to discrimination are denied opportunities to obtain health care services provided to others, with resulting adverse effects on their health status. Moreover, discrimination in health care can lead to poor and ineffective distribution of health care resources, as needed resources fail to reach many who need them. The result is a marketplace comprised of higher medical costs due to delayed treatment, lost wages, lost productivity, and the misuse of people's talent and energy.[304]

We received comments suggesting that we consider either writing a more informative than prescriptive regulation or delaying the regulation. The Department's current experience, however, points to the importance of a regulation that is prescriptive in the sense that it provides concrete guidance. The Department continues to receive many complaints of discrimination and continues to provide technical assistance and outreach in order to promote compliance. In addition, the majority of the comments from the public in response to the proposed rule favored speedy issuance of a strong regulation.

To help address the issues of nondiscrimination in health programs and activities, this regulation seeks to clarify the application of the nondiscrimination provision in the ACA to any health program or activity receiving Federal financial assistance from or administered by HHS or any entity established under Title I. Such clarity will promote understanding of and compliance with Section 1557 by covered entities and the ability of individuals to assert and protect their rights under the law.

In addition, Executive Order 13563 directs Federal agencies to improve regulations and regulatory review by promoting the simplification and harmonization of regulations and to ensure that regulations are accessible, consistent, and easy to understand. Regulations implementing the civil rights laws referenced in Section 1557 contain certain inconsistencies across common areas and subject matters, reflecting, among other things, differences in time and experience when the regulations were issued. The regulation attempts to harmonize these variations where possible.

We received comments asking that the regulation be written in plain language. The approach we adopt in the final rule is to simplify and make uniform, consistent, and easy to understand the various nondiscrimination requirements and rights available under Section 1557, as appropriate.

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[300] Exec. Order No. 12866, 58 FR 51735 (1993).

[301] Exec. Order No. 13563, 76 FR 3821 (2011).

[302] Patient Protection and Affordable Care Act, Public Law 111–148, 1557, 124 Stat. 119, 260, (2010) (codified at 42 U.S.C. 18116).

[303] 42 U.S.C. 18116(c).

[304] Kristen Suthers, American Public Health Association: Issue Brief: Evaluating the Economic Causes and Consequences of Racial and Health Disparities (2008), *http://hospitals.unm.edu/dei/documents/eval_cause_conse_apha.pdf;* Timothy Waldmann, Urban Institute, Estimating the Cost of Racial and Ethnic Health Disparities (2009), *http://www.urban.org/sites/default/files/alfresco/publication-pdfs/411962-Estimating-the-Cost-of-Racial-and-Ethnic-Health-Disparities.PDF;* LaVera M. Crawley, David K. Ahn, and Marilyn A. Winkleby, Perceived Medical Discrimination and Cancer Screening Behaviors of Racial and Ethnic Minority Adults, 17(8), Cancer Epidemiol Biomarkers Prev., 1937–1944 (2008), *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2526181/.*

The analysis that follows is similar to the analysis set forth in the proposed rule, except as specified in each of the sections that follow.

C. Examples of Covered Entities and Health Programs or Activities Under the Final Regulation

This final rule applies to any entity that has a health program or activity, any part of which receives Federal financial assistance from the Department, any health program or activity administered by the Department, or any health program or activity administered by an entity created under Title I of the ACA. The following are examples of covered entities as well as health programs or activities under the final rule.

1. Examples of Covered Entities With a Health Program or Activity, Any Part of Which Receives Federal Financial Assistance From the Department

This Department, through agencies such as the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare and Medicaid Services (CMS), provides Federal financial assistance through various mechanisms to health programs and activities of local governments, State governments, and the private sector. An entity may receive Federal financial assistance from more than one component in the Department. For instance, federally qualified health centers receive Federal financial assistance from CMS by participating in the Medicare or Medicaid programs and also receive Federal financial assistance from HRSA through grant awards. Because more than one funding stream may provide Federal financial assistance to an entity, the examples we provide may not uniquely receive Federal financial assistance from only one HHS component.

(1) Entities receiving Federal financial assistance through their participation in Medicare (excluding Medicare Part B) or Medicaid (about 133,343 facilities).[305] Examples of these entities include:

Hospitals (includes short-term, rehabilitation, psychiatric, and long-term)
Skilled nursing facilities/nursing facilities—facility-based
Skilled nursing facilities/nursing facilities—freestanding
Home health agencies
Physical therapy/speech pathology programs
End stage renal disease dialysis centers
Intermediate care facilities for individuals with intellectual disabilities
Rural health clinics
Physical therapy—independent practice
Comprehensive outpatient rehabilitation facilities
Ambulatory surgical centers
Hospices
Organ procurement organizations
Community mental health centers
Federally qualified health centers

(2) Laboratories that are hospital-based, office-based, or freestanding that receive Federal financial assistance through Medicaid payments for covered laboratory tests (about 445,657 laboratories with Clinical Laboratory Improvement Act certification).

(3) Community health centers receiving Federal financial assistance through grant awards from HRSA (1,300 community health centers).[306]

(4) Health-related schools in the United States and other health education entities receiving Federal financial assistance through grant awards to support 40 health professional training programs that include oral health, behavioral health, medicine, geriatric, and physician's assistant programs.[307]

(5) State Medicaid agencies receiving Federal financial assistance from CMS to operate CHIP (includes every State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(6) State public health agencies receiving Federal financial assistance from CDC, SAMHSA, and other HHS components (includes each State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(7) Qualified health plan issuers receiving Federal financial assistance through advance payments of premium tax credits and cost-sharing reductions (which include at least the 169 health insurance issuers in the Federally-facilitated Marketplaces receiving Federal financial assistance through advance payments of premium tax credits and cost sharing reductions and at least 11 issuers operating in the State-Based Marketplaces that we were able to identify).[308]

(8) Physicians receiving Federal financial assistance through Medicaid payments, "meaningful use" payments, and other sources, but not Medicare Part B payments, as the Department does not consider Medicare Part B payments to physicians to be Federal financial assistance. The Medicare Access and CHIP Reauthorization Act amended Section 1848 of the Act to sunset "meaningful use" payment adjustments for Medicare physicians after the 2018 payment adjustment.

In the proposed rule, we estimated that the regulation would likely cover almost all licensed physicians because they accept Federal financial assistance from sources other than Medicare Part B. We noted that most physicians participate in more than one Federal, State, or local health program that receives Federal financial assistance, and many practice in several different settings, *e.g.,* they may practice in a hospital but also practice privately and develop nursing home plans of care at the local nursing home. We noted that although we have data, by program, for the number of physicians receiving payment from each program, there is no single, unduplicated count of physicians across multiple programs.[309]

In the proposed rule, we provided our best estimate of the number of physicians receiving Federal financial assistance by analyzing and comparing different data sources and drawing conclusions from this analysis. We noted that, based on 2010 Medicaid Statistical Information System data, about 614,000 physicians accept Medicaid payments and are covered under Section 1557 as a result.[310] This figure represents about 72% of licensed physicians in the United States when compared to the 850,000 in 2010.[311] In addition, we noted that physicians receiving Federal payments from non-Part B Medicare sources would also come under Section 1557.[312]

Earlier, before issuing the proposed rule, we identified several grant programs from various Department agencies that fund a variety of health programs in which physicians participate and thus come under Section 1557, such as the National Health Service Corps, HRSA-funded community health centers, programs receiving National Institutes of Health (NIH) research grants, and SAMHSA-funded programs. In the proposed rule, we noted that physicians participating in a CMS gain-sharing demonstration project who receive gain-sharing payments would be covered under Section 1557 even if they did not participate in Medicare and Medicaid or any other health program or activity that receives Federal financial assistance. We also noted that there will be duplication and overlap with physicians who accept Medicaid or Medicare meaningful use payments, or other payments apart from Medicare Part B payments. Nevertheless, we noted that at least some of these physicians add to the total number of physicians reached under Section 1557 because some of them are not duplicates and do not accept Medicaid or Medicare meaningful use payments. We noted that although we do not have an exact number, adding these physicians may bring the total participating in Federal programs other than Medicare Part B to over 900,000.

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[305] U.S. Dep't of Health & Human Servs., Center for Medicare & Medicaid Servs., CMS Provider of Service file, June 2014, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/ProviderofServicesFile.html.*

[306] U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., Justification of Estimates for Appropriation Committee For Fiscal Year 2016, 53, *http://www.hrsa.gov/about/budget/budgetjustification2016.pdf.*

[307] *Id.* at 69.

[308] Qualified Health Plans Landscape Individual Market Medical, Data.HealthCare.gov (2015), *https://data.healthcare.gov/dataset/2015-QHP-Landscape-Individual-Market-Medical/mp8z-jtg7* (last visited May 3, 2016).

[309] 80 FR at 54195.

[310] John Holahan and Irene Headen, Kaiser Commission on Medicaid and the Uninsured, Medicaid Coverage and Spending in Health Reform: National and State-by-State Results for Adults at or Below 133% FPL (2010), *http://kff.org/health-reform/report/report-and-briefing-on-medicaid-coverage-and/.* Estimates are based on data from FY 2010 Medicaid Statistical Information System.

[311] Aaron Young, Humayun J. Chaudhry, Jon V. Thomas, & Michael Dugan, *A Census of Actively Licensed Physicians in the United States, 2012,* 99 no.2 J. Med. Reg. 11 (2013), *https://www.fsmb.org/Media/Default/PDF/Census/census.pdf.*

[312] 80 FR at 54195.

In the proposed rule, when we compared the upper bound estimated number of physicians participating in Federal programs other than Medicare Part B (over 900,000) to the number of licensed physicians counted in HRSA's Area Health Resource File (approximately 890,000), we concluded that almost all practicing physicians in the United States are reached by Section 1557 because they accept some form of Federal remuneration or reimbursement apart from Medicare Part B.[313]

We invited the public to submit information regarding physician participation in health programs and activities that receive Federal financial assistance. We received no comments that would change the estimates that we provided; thus, the analysis in this final rule includes the same numbers of physicians as in the proposed rule.

2. Examples of Health Programs or Activities Conducted by the Department

This final rule applies to the Department's health programs and activities, such as those administered by CMS, HRSA, CDC, Indian Health Service (IHS), and SAMHSA. Examples include the IHS tribal hospitals and clinics operated by the Department and the National Health Service Corps.

3. Examples of Entities Established Under Title I of the ACA

This final rule applies to entities established under Title I of the ACA. According to the CMS Center for Consumer Information and Insurance Oversight (CCIIO), there are Health Insurance Marketplaces covering 51 jurisdictions: (17 State-based-Marketplaces and 34 Federally-facilitated Marketplaces). The final rule covers these Health Insurance Marketplaces.

II. Costs

It is important to recognize that this final rule, except in the area of sex discrimination, applies pre-existing requirements in Federal civil rights laws to various entities, the great majority of which have been covered by these requirements for years. Because Section 1557 restates existing requirements, we do not anticipate that covered entities will undertake new actions or bear any additional costs in response to the issuance of the regulation with respect to the prohibition of race, color, national origin, age, or disability discrimination, except with respect to the voluntary development of a language access plan. However, we also note that the prohibition of sex discrimination is new for many covered entities, and we anticipate that the enactment of the regulation will result in changes in action and behavior by covered entities to comply with this new prohibition. We note that some of these actions will impose costs and others will not.

Section 1557 applies to the Health Insurance Marketplaces. We note that these entities, along with the qualified health plan issuers participating in the Health Insurance Marketplaces, are already covered by regulations issued by CMS that prohibit discrimination on the basis of race, color, national origin, sex, gender identity, sexual orientation, age, or disability. Thus, we note that the impact of Section 1557 on these entities is limited.

We received a few comments that indicated that the costs of compliance may be more than anticipated in the proposed rule. We have revised the analysis in this final rule based upon the comments and upon an updated statistical review of the health programs and activities.

The following regulatory analysis examines the costs and benefits that are attributable to this regulation only.

We first analyze the costs we expect the final rule to create for covered entities. We anticipate that the final rule will place costs on the covered entities in the areas of: (1) Training and familiarization, (2) enforcement, (3) posting of the nondiscrimination notice and taglines, and (4) revisions in policies and procedures, and may place costs on covered entities in the voluntary area of development of a language access plan. Then we examine the potential benefits the rule is likely to produce. In the subsequent analyses of costs in this RIA and the Regulatory Flexibility Act (RFA), we use data sets from the Census Bureau[314] and BLS[315] for estimating burdens.

A. Assumptions

In the proposed rule, we made the following cost assessment based on certain key assumptions, which include: (1) We assume that promulgation of this regulation will trigger voluntary activity on the part of covered entities that would not have occurred absent the promulgation of the regulation—which generates both costs and corresponding benefits; (2) to the extent that certain actions are required under the final rule where the same actions are already required by prior existing civil rights regulations, we assume that the actions are already taking place and thus that they are not a burden imposed by the rule; (3) although the regulation does not require training at any specific time, we assume that covered entities may voluntarily provide one-time training to some employees on the requirements of the regulation at the time that the regulation is published; and (4) we assume that employers are most likely to train employees who interact with the public and will therefore likely train between 40% and 60% of their employees, as the percentage of employees that interact with patients and the public varies by covered entity. For purposes of the analysis, we assume that 50% of the covered entity's staff will receive one-time training on the requirements of the regulation. We use the 50% estimate as a proxy, given the lack of certain information as described below. For the purposes of the analysis, we do not distinguish between employees whom covered entities will train and those who obtain training independently of a covered entity.

B. Training and Familiarization

In the proposed rule, we counted the cost of training on all aspects of the regulation, not only on the new responsibilities under the regulation, as we believe covered entities will want to offer comprehensive training to employees, recognizing that refresher training can provide value. We invited comment on whether we should count only the cost of training on new responsibilities under the regulation. The comments we received supported our assumption regarding training on all aspects of the regulation, and therefore the final rule keeps this assumption.

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[313] The Area Health Resource File itself double counts physicians who are licensed in more than one state. *See infra* discussion below at II.C.1.a.

[314] U.S. Census Bureau, Statistics of U.S. Businesses, *http://www.census.gov/econ/susb/* (last visited May 3, 2016).

[315] U.S. Dep't of Labor, Bureau of Labor Statistics, May 2015 National Occupational Employment and Wage Estimates, *http://www.bls.gov/oes/2014/may/oes_nat.htm (last visited May 3, 2016).*

In the proposed rule, we also assumed that covered entities will provide some workers (not all workers) a one-time awareness or familiarization training regarding the requirements in the regulation at the time of its issuance. We noted that many employees may work "behind the scenes" at large entities, and may not have contact with patients or the general public or otherwise have duties impacted by the final rule's requirements and therefore may have little need for training. However, we noted that we are uncertain which employees those are. Furthermore, we noted that we do not know whether an entity rotates employees into different positions that may have patient contact or relevant duties, or whether, over time, an employee will switch to a position that places him or her in such a position, which may create a need for training. Although we received one comment suggesting that we include all employees in the training, the comment did not provide evidence or data to support including all employees. Otherwise, we received no comments to the contrary; therefore, the final rule makes the same assumption that the proposed rule did, that covered entities will provide some (not all) workers a one-time familiarization training.

In the proposed rule, we also noted that we lack information on State and local regulations that may require employees to receive training on civil rights provisions and whether those provisions are more or less rigorous than the ones we propose. Thus, workers in covered entities in State and local jurisdictions with civil rights provisions more robust than the ones we propose may need only minimal training. In State and local jurisdictions where civil rights provisions are not more robust, workers may need more training. As stated above, because we lack data on covered entities' training practices, we are assuming that covered entities will voluntarily provide training on the final rule for between 40% and 60% of their staffs. Further analysis of state requirements revealed that the states do vary in the robustness of their civil rights requirements, as we assumed in the proposed rule. Therefore, we chose 50% of the employees, the average between 40% and 60%.

Based on comments we received, we added a category of training, for a one-time familiarization by a manager, after the final rule has been published. The manager will need to study and understand the regulation well enough to make assessments of how the entity will promote compliance with the rule, including assessing the training needs of the staff and the costs associated with the training.

In the following section, we identify the pool of workers and staff that we anticipate may need education about the final rule. Next, we identify the covered entities that may choose to train their staffs to provide this knowledge. Last, we estimate the costs of the training materials and the worker time that will be spent in training.

1. Number of Individuals Who Will Receive Training

a. Health Care Staffs and Managers

The first category of health care staff that may receive training is comprised of health diagnosing and treating practitioners. This category includes physicians, dentists, optometrists, physician assistants, occupational, physical, speech and other therapists, audiologists, pharmacists, registered nurses, and nurse practitioners. The BLS occupational code for this grouping is 29–1000 and the 2014 reported count for this occupational group is approximately 4.8 million.

The second category of health care staff that we assume will receive training is comprised of degreed technical staff (Occupation code 29–2000) and accounts for 2.9 million workers. Technicians work in almost every area of health care: From x-ray to physical, speech, psychiatric, dietetic, laboratory, nursing, and records technicians, to name but a few areas.

The third category of health care staff that we assume will receive training is comprised of non-degreed medical assistants (Occupation code 31–0000), and includes psychiatric and home health aides, orderlies, dental assistants, and phlebotomists. Health care support staffs (technical assistants) operate in the same medical disciplines as technicians, but often lack professional degrees or certificates. We refer to this workforce as non-degreed compared to medical technicians who generally have degrees or certificates. There are approximately 3.9 million individuals employed in these occupations.

The fourth category of health care staff that we assume will receive training is health care managers (approximately 0.3 million based on BLS data for occupation code 11–9111). Because we assess costs of familiarization with the regulation for one manager at each entity, we assume that those managers will have already become familiar with the regulation and will not need additional training.

The fifth category of health care staff that we assume will receive training is office and administrative assistants—Office and Administrative Support Occupation (Occupation code 43–0000). These workers are often the first staff patients encounter in a health facility and, because of this, covered entities might find it important that staff, such as receptionists and assistants, receive training on the regulatory requirements. Approximately 2.7 million individuals were employed in these occupations in health facilities in 2014.[316]

One comment asked that outreach workers be explicitly included as a category to be trained. We assume that outreach workers are included in the five categories listed above, especially in the manager category.

Below is a summary table of individuals employed in the health care sector.

TABLE 1—HEALTH CARE EMPLOYEES WHO MAY NEED TRAINING

Health diagnosing and treating practitioners	4,833,840
Degreed technicians	2,876,000
Non-degreed technicians	3,940,500
Medical and health services managers	310,320
Office and administrative support staff	2,747,330
Total	14,707,990

b. Employees Working for the Federally-Facilitated Marketplaces and State-Based Marketplaces and Issuers in Those Marketplaces

We have data from CMS/CCIIO on the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces.[317] We assume that many issuers that operate in the Federally-facilitated Marketplaces also operate in the State-based Marketplaces. However, to the extent there are issuers who operate in a State-based Marketplace$^{\text{SM}}$

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[316] U.S. Dep't of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2014 National Occupational Employment and Wage Estimates, United States, *http://www.bls.gov/oes/2014/may/oes_nat.htm* (last visited May 3, 2016). This code includes health care sector data for health care and social assistance (including private, State and local government hospitals).

[317] Qualified Health Plans Landscape Individual Market Medical (2015), *supra* note 308.

only, an estimate of their employees will not be included in our count of issuers (derived from the CCIIO tables of issuers participating only in the 34 jurisdictions with Federally-facilitated Marketplaces). We are basing our calculations on the number of employees working for those issuers participating in the Federally-facilitated Marketplaces and we assume, as noted above, that some of the same issuers and employees serve the State-based Marketplaces. Determining the number of employees working for issuers participating in the Health Insurance Marketplaces is challenging because we have no data directly linking the number of employees to our data on participating issuers in the Federally-facilitated Marketplaces. Consequently, we must impute the number of employees working for issuers participating in the Federally-facilitated Marketplaces and, by extension, employees working for issuers in State-based Marketplaces.

We performed this imputation by first identifying the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces. To determine the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces, we looked at the 2015 Qualified Health Plan Landscape Individual and Small Business Health Options Program Market Medical files.[318] The Qualified Health Plan Landscape Individual Market Medical file contains over 100,000 line items, and the Small Business Health Options Program Market Medical file contains over 50,000 line items listing each Federally-facilitated Marketplace℠ plan for each county by metal level (bronze, silver, gold, and platinum) and catastrophic plans provided by each issuer. To determine the number of issuers in the individual and Small Business Health Options Program Marketplaces, we removed all plan line items to reduce the count to an unduplicated count of the issuers in the Federally-facilitated Marketplaces. We identified 155 individual plan issuers and 14 issuers in the Small Business Health Options Program that only issued group plans to employees of employers participating in the Small Business Health Options Program. Our total count of 169 issuers differs from the CCIIO sources, which counted issuers in each State in which they operated. For example, a national issuer such as Aetna that offers coverage through Federally-facilitated Marketplaces operating in several States was counted separately by CCIIO for each State in which it was qualified, whereas we counted it only once.[319]

In addition to 169 issuers participating in Federally-facilitated Marketplaces, we are aware of 11 issuers participating only in the State-based Marketplaces. Thus, we calculated that the total number of issuers included in the analysis of covered issuers equals 180.

We next analyzed the number of employees working in the health insurance industry in the following way. Using Census Bureau 2011 payroll and employment data (the latest data available) for North American Industry Classification System 524114—Direct Health Insurance,[320] we attempted to match the number of employees to the health insurance entities. The Census data permitted us to divide all health insurance issuers into "large" (500 or more employees) and "small" (fewer than 500 employees) issuers, and from that we were able to estimate the number of employees for large and small issuers.

The Census data shows 805 small issuers and 180 large issuers. The ratio of small to large issuers is about 4.5 small issuers for every large issuer. We assume the ratio of small to large issuers in the Health Insurance Marketplaces is approximately the same as the ratio in the Census table. We asked for public comment on this assumption, and we received no comments to the contrary.

Applying this ratio to the issuers in the Federally-facilitated Marketplaces, we get 131 small issuers and 38 large issuers. We assume that the 11 issuers (for which we have data and have thus identified) operating in the State-based Marketplaces are likely to be classified as small, based on Census workforce data. Therefore, we are adding them to the 131 small issuers identified above, bringing the total number of small issuers to 142.

Based on the Census data, the average number of employees in a small issuer is 34 and the average number of employees in a large issuer is 2,300. If we multiply the number of issuers by the number of employees, there are 4,828 employees of the 142 small issuers and 87,400 employees of the 38 large issuers. The combined total number of employees for small and large issuers in the Marketplaces is estimated to be 92,228 employees.

With respect to the majority of issuers operating in a State-based Marketplace℠ that we have not been able to identify but would also be subject to the regulation, we do not have any direct data. However, the workforce data we have from the Census tables covers employees regardless of their work site. If any of the 169 issuers identified above operating in the Federally-facilitated Marketplaces also operate in the State-based Marketplaces, then some portion of the nearly 92,000 employees imputed to be working for the issuers in the Federally-facilitated Marketplaces may also be working for issuers operating in the State-based Marketplaces. Thus, in effect, we are including employees working for issuers that operate in both the State-based Marketplaces and the Federally-facilitated Marketplaces in our count of employees who likely will receive training on the regulation.

At the same time that we include employees who work for issuers operating in both the Federally-facilitated Marketplaces and State-based Marketplaces, we lack direct data on issuers participating only in State-based Marketplaces. We are not able to include employees that work for insurance issuers that operate only in State-based Marketplaces, such as New York or California, which would be subject to the proposed rule. We invited public comment on ways we could identify issuers that participate only in State-based Marketplaces and the number of employees they employ. We did not receive any comments that identified ways we can better identify these issuers.

A third category of workers who may need to be trained are navigators receiving Federal financial assistance to support the functions they perform in Federally-facilitated Marketplaces, such as assisting applicants to enroll in qualified health plans through the Marketplace℠. CMS has awarded grant funding to 100 Navigator entities.[321] In the proposed rule, we estimated that 2,797 navigators worked for 92 Navigator entities, which implies 30.4 employees per entity. We lacked data on the number of employees of these Navigator entities, and we thus applied the previous estimate of 30.4 employees per Navigator entity to estimate in the final rule that 3,040 employees work for these entities.

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[318] *Id.*

[319] We count the issuer only once because we assume the same enterprise will minimize training costs by preparing the same training materials for all its employees nationally.

[320] U.S. Census Bureau, Statistics of U.S. Businesses (SUSB) (2011), *http://www.census.gov/econ/susb/.*

[321] CMS awards $67 million in Affordable Care Act funding to help consumers sign-up for affordable Health Insurance Marketplace℠ coverage in 2016, *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-09-02.html* (last visited May 3, 2016).

We invited public comment on our approach to estimating the number of employees per issuer based on the Census data and sought any public information on issuers who operate only in State-based Marketplaces. We did not receive comments that changed our assumptions regarding types and numbers of employees working for Marketplaces. Thus, the final rule applies the estimate of the number of navigators per Navigator entity to the most recent number of Navigator grantees.

c. Medicaid and State and Local Health Department Employees

The Census Bureau State government payroll and employment data for 2012 shows the number of full-time employees working in State hospitals and departments of health as 531,251.[322] The State Medicaid Operations Survey: Fourth Annual Survey of Medicaid Directors reports that State Medicaid agencies employed between 27 and 3,853 full-time employees with a median workforce level of 455 employees.[323] Multiplying the median level of workers by 56 Medicaid agencies adds 25,480 workers to the number of State health and hospital workers in health departments, bringing the total to 556,731 employees. (Although a more appropriate method of calculating the total would be to use the mean as the multiplier, OCR used the median because the mean was unavailable.) However, this number double counts medical personnel that were previously counted as discussed in part I.C.1.a (regarding health care staffs and managers who will receive training) in this RIA.

To address this problem, we looked at the BLS industry data for North American Industry Classification System code 999201: State government, including schools and hospitals, we identified 442,680 personnel employed by State governments.[324] Subtracting this number from the 556,731 employees we identified employed in State government health services and Medicaid programs, results in 114,051 additional State employees who may obtain training on the provisions of the regulation.

d. Non-Health Care Personnel in Pharmacies

The 2012 Census data for all U.S. industries identifies 43,343 pharmacy establishments. The number of employees presented in the Census data includes both pharmacists and non-pharmacist personnel. At this point, we must refer back to the BLS data on the number of health care workers reported for 2014 because the BLS data divides the pharmacy workforce by occupation. The number of employees that BLS reports were employed in pharmacies for 2014 is 708,660. The number of health care workers discussed in subsection II.C.1.a. above includes 348,190 individuals counted above in occupation codes 11–9111, 29–0000 and 31–0000 reported to be working in pharmacies.[325] Because we already counted the costs of health care workers employed in pharmacies in the analysis of health care staff, to achieve a more accurate estimate of the number of non-health care pharmacy workers, we must subtract the 348,190 health care staff from the total workforce BLS reports. Removing health care staff from the BLS data yields a net of 360,470 non-health care pharmacy workers in pharmacies who may receive training on the final rule.

The following table shows the total number of employees whom we estimate will receive training; that is, the table shows the 50% of total workers whom we estimate may receive training. The table does not include HHS employees conducting HHS health programs or activities because there are roughly 65,000 HHS total employees and many of these employees do not work in health programs or activities administered by HHS. For those employees who do work in health programs or activities administered by HHS, many may not have direct beneficiary contact. Given these limitations, we estimate the number of employees added would be small and have little impact on overall cost.

TABLE 2—WORKERS WHO MAY RECEIVE TRAINING ON THE REGULATION

Medical health staffs and managers	7,216,494
Employees working for 180 issuers in the Health Insurance Marketplaces	46,114
State health employees	55,442
Navigators	1,520
Pharmacy workers (excluding health care personnel)	180,235
Total	7,637,306

2. Number of Covered Entities That May Train Workers

Just as there are a number of data sources for counting workforce, there are various sources for counting the number of health care entities. Many covered entities are controlled or owned by a single corporate entity, and one can count each individual entity separately or count only the single corporate enterprise. For example, a multi-campus facility or vertically integrated entity that owns a hospital, a nursing home, and a home health agency and also operates an accountable care organization could count each of these entities separately—as does Medicare—or count them only once, with each entity treated as part of the corporate entity. At this point, we make two assumptions: (1) Albeit not required to do so by the regulation, each covered entity will provide some training to its staff on the requirements of the regulation; and (2) when entities are controlled or owned by a corporate entity, the corporate entity will supplement or make any desired modification to the OCR training materials and distribute the training materials. We believe this last point to be especially true because rather than have each entity prepare its own training materials, the corporate entity is more likely to prepare one set of training materials and distribute the materials to its individual entities. This is because the corporate entity saves money by preparing a limited set of training materials and assures uniform quality and consistency in its policies across all its entities. It is also possible that some local health centers in a State may be managed from a central location that handles logistics and training materials. Therefore, we propose using the 2012 Census table that presents the number of entities, referred to as firms in the Census tables, to count the number of health care entities. In the Census data, a corporate entity is referred to as a "firm" and the corporation's facilities are "establishments." When a firm has one establishment, the establishment is the firm.

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[322] U.S. Census Bureau, Government Employment & Payroll (2013), *http://www.census.gov/govs/apes/*.

[323] Nat'l Ass'n of State Medicaid Dirs, State Medicaid Operations Survey: Fourth Annual Survey of Medicaid Directors, at 5 (Nov. 2015) *http://medicaiddirectors.org/wp-content/uploads/2015/11/namd_4th_annual_operations_survey_report_-_november_2_2015.pdf*.

[324] U.S. Dep't of Labor, Bureau of Labor Statistics, May 2015 National Occupational Employment and Wage Estimates by ownership, *http://www.bls.gov/oes/2014/may/oes_nat.htm* (last visited May 3, 2016).

[325] U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., Area Health Resource Files, *http://ahrf.hrsa.gov/* (last visited May 3, 2016). The Area Health Resource File reports 272,022 pharmacists licensed in 2014.

Another difficulty we face in using these data sources is that the Census data captures all entity types that fit the definition of a health care service entity, including entities such as private retirement communities that are unlikely to receive Federal financial assistance and thus would not be covered by Section 1557. In our use of the Census data, we attempted to exclude types of entities that are not likely to receive Federal financial assistance by excluding retirement communities and other similar type entities in the file, but we have included entities that may receive Federal financial assistance, such as community health centers and residential centers for individuals with intellectual disabilities.

To test our success in producing a list of covered entities from the Census data, we compared the number of entities we selected from the Census data and the number of entities included in the CMS Provider of Service file. However, to make the lists comparable, we had to remove the count of Clinical Laboratory Improvement Act laboratories from the CMS Provider of Service data files. There are close to 450,000 Clinical Laboratory Improvement Act laboratories located in hospitals, clinics, outpatient centers, and doctors' offices. Only a few thousand of these laboratories serve the public. The majority of laboratories serve the facility in which they are housed—including them in our comparison would grossly distort this comparison.

If we add the entities in the Provider of Service file (excluding Clinical Laboratory Improvement Act laboratories) and the number of community health centers to our list of affected entities that are not included in the Provider of Service file, we get a total of 134,543 entities. Using the Census data, minus the categories for medical laboratories, we obtain a total of 139,164 covered entities. It is evident that these numbers are very similar. However, as discussed earlier, we propose using only the number of firms for the analysis of the number of entities possibly conducting training, that is, 70,384 firms. As noted, we believe firms and not establishments will modify or supplement materials and train employees.

In addition to the firms we include from the Census file, we must add physicians' office firms and pharmacy firms because they may also need to train some workers. Physicians' office firms and pharmacy firms are generally referred to as physician group practices and pharmacy chains.

Below we present the types and number of firms that we estimate will take part in the training for the regulation.

TABLE 3—NUMBER OF HEALTH CARE ENTITY FIRMS EXPECTED TO TAKE PART IN TRAINING

NAIC	Entity type	Number of firms
62142	Outpatient mental health and substance abuse centers	4,987
621491	HMO medical centers	104
621492	Kidney dialysis centers	492
621493	Freestanding ambulatory surgical and emergency centers	4,121
621498	All other outpatient care centers	5,399
6215	Medical and diagnostic laboratories	7,958
6216	Home health care services	21,668
6219	All other ambulatory health care services	6,956
62321	Residential intellectual and developmental disability facilities	6,225
6221	General medical and surgical hospitals	2,904
6222	Psychiatric and substance abuse hospitals	411
6223	Specialty (except psychiatric and substance abuse) hospitals	373
6231	Nursing care facilities (skilled nursing facilities)	8,623
44611	Pharmacies and drug stores	18,852
6211	Offices of physicians	185,649
524114	Insurance Issuers	180
	Navigator grantees	100
Total Entities		275,002

3. Training and Familiarization Costs

a. Cost of Training Materials and Presentations

There are two components to the cost of training the workers we identified in the previous section: (1) The cost of training materials that is based on the number of covered entities identified in the previous section; and (2) the cost of employee time spent in training.

OCR estimates, based on its experience of training employees on other regulations it enforces, that training employees on this regulation will take about one hour of an employee's time. Based on discussions with firms that develop training materials, we estimate that developing or presenting materials for a one-hour course would cost about $500. However, before the effective date of the rule, OCR will provide covered entities with training materials that will cover the key provisions of the regulation that can be used by entities in conjunction with their own training materials. We estimate that OCR preparing the training materials on the regulation will substantially reduce the material preparation burden to covered entities and reduce the cost by about three quarters, or about $375 per entity. Therefore, the costs to entities will equal $125 multiplied by the number of entities that will prepare and present training materials. Based on its experience in preparing training materials for other civil rights and HIPAA regulations, OCR expects to spend $10,000 to develop training materials that will prepare health care workers and managers to effectively implement the Section 1557 regulation.

Training materials can be presented in a number of ways. A common method for offering training materials is through e-courses that are distributed over an entity's computer network. Another method is to offer lectures to selected employees/staff and then have attendees present the materials to their co-workers as part of train-the-trainer programs. For small entities, one lecture session may be given to all employees. Regardless of presentation mode, we estimate that the cost of training via an e-course will be the same as the cost of training through a lecturer for a train-the-training approach: $125 per entity.

Applying the $125 per course materials to the number of firms ($125 × 275,002)—including the 169 health insurance issuers—equals $34.4 million for the cost of developing training materials.

b. Cost of Employee Time

The next step is to compute the cost of employee time for training and familiarization. This involves taking the hourly wage rate times the amount of time that a new activity will require, times the number of employees expected to undertake the activity as a result of the rule. We use data from the BLS on median wage rates by occupation to estimate wages throughout this analysis. We are uncertain about how many employees identified in the workforce above will actually seek and obtain training and how many firms in the health sector will offer training. However, for the purposes of this analysis we assume that all firms may offer some training to their staffs, but because the training is voluntary, and because only a portion of employees who have direct patient contact or otherwise have duties impacted by the regulation may require or take training, we assume that 50% of employees will receive training. We assume that training will require an average of one hour of time for each participating employee.

The occupation code 29–1000 (health care practitioners) applies to the 4.8 million professional staff and degreed technical staffs we discussed above. The BLS reports the median hourly wage for this code as $36.26. We estimate one hour of a worker's time would be required for training. To this amount we must add 100% for fringe benefits and overhead, which yields an adjusted hourly wage per employee of $72.52. Assuming that half of the 4.8 million health care practitioners identified earlier receive or obtain training (2.4 million workers), and multiplying this number by the hourly employee wage plus fringe benefits and overhead for one hour equals slightly more than $175.3 million in training costs for practitioners.

We note that one commenter suggested that we use a factor higher than 100% to adjust wages for overhead and benefits. However, the commenter's argument is based on Federal overhead rates for contracts, and not evidence of the resource costs associated with reallocating employee time. As a result, we do not adopt the commenter's recommendation, and we continue to use the Department's standard of 100% for overhead and fringe benefits.

For the degreed health care work force in occupation 29–2000, the median hourly wage is $19.92. Adding 100% for fringe benefits and overhead equals $39.84. The total training cost for one hour of training for half of the 2.9 million degreed technical staff (1.44 million workers) is about $57.3 million. In addition, we must add the cost of training non-degreed staff (reported in occupation 31–0000) who earn a median hourly wage of $12.71. Adding 100% for fringe benefits and overhead to the $12.71 median hourly wage rate yields an adjusted wage of $25.42. Multiplying this amount by half of the 3.9 million workforce yields a cost of $50.1 million.

To these amounts we must add the cost associated with familiarization and training for the medical and health service managerial staff, of which there are 300,320 individuals with a median hourly pay rate of $44.62. Adding 100% for fringe benefits and overhead gives us an adjusted hourly wage of $89.24. We assume that an average of one person in this occupation will spend an average of two hours becoming familiar with the final rule's requirements upon its publication at each of the 275,002 entities covered by the rule. These assumptions imply familiarization costs of $49.1 million. We assume that half of the remaining managers receive training. This implies that 12,659 managerial staff will receive an hour of training, which results in a cost of $1.1 million. This implies that total costs for training and familiarization for this occupation category comes to $50.2 million.

The cost of training occupation code 43–0000, office and administrative support workers employed in covered health care entities, is the product of the median hourly rate of $15.52 adjusted for fringe benefits and overhead multiplied by the 2.7 million workers reported for North American Industry Classification System code 62: Health Care and Social Assistance (including private, State, and local government hospitals). Adding 100% for fringe benefits and overhead to the $15.52 equals $31.04. Multiplying the pay rate by half the number of support and administrative personnel equals $42.6 million.

The 2013 BLS data for North American Industry Classification System pharmacies and drugstores reports a total workforce of 708,660 workers. As with the analysis for State employees, we must remove the 348,190 health care workers who are already counted in our training costs analysis of the health care workforce. To avoid double counting training costs for these occupations, we removed them from the count of the pharmacy workforce. (The entities that employ these workers will still bear the cost for training them.) Their median weighted wage is $17.22, which is derived from BLS data for medical pharmacy personnel, and the cost associated with an hour of their time is $34.44 after adjusting for overhead and benefits. We estimate $6.0 million in costs for training half of these medical pharmacy personnel.[326]

For the 360,470 non-medical pharmacy personnel, their weighted median hourly rate for pharmacy employees is $11.87, which is derived from BLS data for non-medical pharmacy personnel. After adjusting for overhead and benefits, the cost of one hour of time in this category is $23.74. We estimate $4.3 million in costs for training half of these non-medical pharmacy personnel.

For the 3,040 navigators, we lack data to determine their wages. As a proxy, we use the wage rate for medical and health service managerial staff, with a median hourly pay rate of $44.62. Adding 100% for fringe benefits and overhead gives us an adjusted hourly wage of $89.24. We estimate $0.1 million in costs for training half of these navigators.

For the remaining entities for which we cannot use BLS data, we must use the industry payroll and employment Census data. To arrive at an estimate of the cost of time for training employees of health insurance issuers and State health and Medicaid agencies, we must divide the total annual payroll reported for these entities by the total number of employees and divide that number by the annual hours paid (2,080 hours), adjusted for fringe benefits and overhead.

For workers employed by the issuers participating in the Health Insurance Marketplaces, it was necessary to determine the hourly wage rate for workers employed in small and large issuers as we have described them above. The total number of workers in small entities (fewer than 500 workers) is 27,269 and the annual payroll is $1.68 billion. The average wage per employee is $61,895. Using the 2,080 hours for the annual number of work hours, we obtain an hourly rate of $29.76.

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[326] Determining the cost to train employees other than pharmacists and medical staff who work in pharmacies requires use of the Bureau of Labor Statistics industry data for North American Industry Classification System. These data show that for 2013, 348,380 medical practitioners, technologists and medical support staff were employed in pharmacies and drug stores. U.S. Dep't of Labor, Bureau of Statistics, Occupational Employment Statistics, *supra* note 316.

Assuming that the payroll amounts reported in the Census data do not include fringe benefits and overhead, we add 100% to the hourly rate to yield $59.51 per hour. Multiplying this amount by half of the 4,454 employees in small issuers equals $132,540 in training costs.

The total number of employees employed by large issuers (500 or more) is 415,017 and the annual payroll is $30.8 billion. The average annual wage is $74,219. Dividing this figure by 2,080 hours yields an hourly wage rate of $35.68. Multiplying by 100% for fringe benefits and overhead yields $71.36. Multiplying this amount by 50% of the 87,400 workers equals slightly more than $3.12 million in training costs.

For State government workers employed in welfare, health, and hospital services, we divided the total number of workers the 2012 Annual Census Bureau reported (873,289 employees) into the monthly payroll reported for the period ($3,774,775,691).[327] On an annual basis, the average salary per employee equals $51,870. The hourly rate equals $24.94 and multiplied by 100% for fringe benefits and overhead yields $49.87 per worker for training costs.

In the State Medicaid Operations Survey: Second Annual Survey of Medicaid Directors, States reported the median number of full-time Medicaid employees is 421. Using this number multiplied by the 53 Medicaid agencies in the 50 States, the District of Columbia, Puerto Rico, Guam, and the other territories, we added 22,313 workers to the total of health and hospital workers reported in the Census data, bringing the total number of workers in covered State government entities to 553,564. We then subtracted the 442,680 medical personnel we accounted for in the training costs for all health care personnel and therefore were considered to be duplicative of the medical personnel previously counted in our analysis of medical staff workforce (occupations 29–1000, 29–2000 and 31–0000). This left a net of 110,884 State employees receiving training. Taking half of this number and multiplying it by $49.87 equals a training cost of slightly more than $2.76 million.

Although we removed the cost of training the 442,680 medical personnel from the State training cost analysis to avoid double counting training costs, the cost of training half the medical staff may still fall to the States where they are employed. We estimate the cost to train State medical personnel to be approximately $11.1 million.[328]

As noted above, total familiarization costs are estimated to be $49.1 million. The following table summarizes the training costs we estimate for this rule.

TABLE 4—TOTAL TRAINING COSTS

	Number of entities/workers	Cost (millions)
Training preparation costs ($125/entity)/entity	*275,002	$34.4
Health care staff and managers training	*7,214,862	326.9
Small Issuers in the Health Insurance Marketplace℠ training	2,414	0.1
Large issuers in the Health Insurance Marketplace℠ training	43,700	3.1
Navigators	1,399	0.1
State health, hospital and Medicaid worker training	55,442	2.8
Pharmacy worker training	180,235	4.3
Total	7,498,052	371.7

* Not included in column total.

C. Notification and Other Procedural Requirements

1. Designation of Responsible Employee and Adoption of Grievance Procedures

Pursuant to the regulations implementing Section 504, recipients of Federal financial assistance with 15 or more employees are required to designate a responsible employee to coordinate compliance with respect to nondiscrimination requirements and to have grievance procedures to address complaints of discrimination under this law. Of the 275,002 covered entities, approximately 15% employ more than 15 employees, resulting in approximately only slightly more than 41,250 covered entities being required to have grievance procedures and designate a responsible official. Thus, all recipients of Federal financial assistance with 15 or more employees are already expected to have in place grievance procedures and a designated employee to coordinate their compliance responsibilities. The rule standardizes the requirement to designate a responsible employee and adopt grievance procedures across all bases of discrimination prohibited under Section 1557.

To implement the rule, a recipient of Federal financial assistance could increase the responsibilities of an already-designated employee to handle compliance with the rule's nondiscrimination requirements. In addition, a recipient of Federal financial assistance could increase the scope of existing grievance procedures to accommodate complaints of discrimination under all bases prohibited under Section 1557. The costs associated with these requirements are the costs of training the designated employee on the employee's increased responsibilities and the costs associated with modifying the existing grievance procedures to reflect the additional bases of race, color, national origin, sex, and age. Here we are referring to employee training to perform their specific enforcement responsibilities, not one-time training in the provisions of the final rule described in the training section above. We also note that grievance officials will probably receive specific training on their new responsibilities and that covered entities will probably provide this additional training and absorb the costs, which are expected to be de minimis. Many covered entities already may be using their existing grievance procedures to address the additional cases covered under Section 1557.

State-based Marketplaces are required to designate an employee to handle compliance responsibilities and to adopt grievance procedures under the ADA. The duties of the employee and the grievance procedures could be modified to reflect all the bases covered under Section 1557.

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[327] U.S. Census Bureau, Government Employment & Payroll, *http://www.census.gov/govs/apes/* (last visited May 3, 2016).

[328] We calculated the cost of training the medical personal using the weighted median hourly rate, $47.22, multiplied by the 446,210 medical staff identified as employed in State governments.

We have not estimated the additional costs of training grievance officials on their individual enforcement responsibilities, but we believe such cost would be absorbed in general training costs of all employees on their job responsibilities. Costs associated with modifying existing grievance procedures are covered in the section of the analysis on enforcement.

2. Notice Requirement

The implementing regulations of Title VI, Section 504, Title IX, and the Age Act require recipients of Federal financial assistance and, in the case of Section 504, the Department, to notify individuals that recipients (and, under Section 504, the Department) do not discriminate. The content of the nondiscrimination notices varies based on the applicable civil rights law.

The final rule harmonizes notification requirements under Title VI, Section 504, Title IX and the Age Act, and standardizes the minimum information for a notice. The final rule also requires initial and continuing notification of individuals. OCR drafted a sample notice (located in Appendix A to Part 92) in English that meets the requirements and will translate that notice into 64 additional languages, in advance of the effective date of this rule. Covered entities have discretion to use the OCR sample notice or their own notice, if preferred, and to post the notice in non-English languages.

As all Section 1557 covered entities will need to create or update an existing notice of nondiscrimination, all covered entities can discharge their responsibilities under § 92.8(a) by replacing their current notices with the sample notice developed by OCR (found in Appendix A), available to all covered entities pursuant to § 92.8(c). Using the sample OCR notice means that covered entities will not have to compose their own notices; we expect nearly all covered entities will use the sample OCR notice.

All covered entities will incur costs, however, to implement § 92.8(a) of the final rule, which requires "initial and continuing" notification. Such notification is expected to involve:

- Downloading the notice from the OCR Web site;
- Printing copies of the notice for posting;
- Posting hard copies of the notice in public spaces of the office or facility; and
- Posting the notice on the entity's Web site, if it has one.

While many costs to comply with this rule are incurred at the entity level, the costs of downloading, printing, and posting the notice are incurred at the establishment level. There are approximately 275,000 covered entities covered by this final rule. According to 2012 Census data, these covered entities are associated with 405,534 establishments. We estimate that a clerical worker at each establishment would spend an average of one minute downloading the notice from the OCR Web site, an average of one minute printing copies of the notice for posting, an average of five minutes posting hard copies of the notice in public areas, and an average of ten minutes total between preparing the OCR notice for posting on the facility's Web site and posting the notice on the Web site. This implies that the estimated cost associated with posting is $8.79 ($31.04 per hour × 17 minutes × 1 hour per 60 minutes) per establishment, which implies that the total estimated cost associated with this requirement is $3.6 million ($8.79 per establishment × 405,534 establishments).

Covered entities will need to update their significant publications and significant communications to include the new notice. However, as noted above, OCR is allowing entities to exhaust their current publications, rather than do a special printing of the publications to include the new notice. When covered entities restock their printed materials, they will be expected to include in those printed materials the notice that OCR will provide with this final rule.

Because we are permitting covered entities to exhaust their existing stock of publications with the current notices before using the new notice, we conclude that the notice requirement imposes no resource costs related to including updated notices in the publications.

Section 92.8 provides covered entities discretion to post the OCR sample notice of nondiscrimination in non-English languages, which can include languages that differ from OCR's list. In addition, covered entities can draft and translate their own notice in however many languages they choose, if they prefer.

We examined CMS contractual cost for translating a one page notice into 13 languages. It was $1,000 per page. Based on this figure, we expect total costs to the government to be limited to $64,000 to translate the notice into 64 languages and place the translated notices on OCR's Web site. The sample notice is one page long. In addition, we expect total costs to the government for translating the statement of nondiscrimination for small-size publications to be $50 for each of the 64 languages. We count the nondiscrimination statement as .05 pages long.

Although not required, we expect that many covered entities would choose to post the OCR-provided notice in one or more non-English languages on their Web sites, in their physical office space, and in certain publications they may have. We do not know how many covered entities would take this action or how many non-English language versions of the notice they would choose to post, or where they would make the non-English versions of the notice available.

Section 92.8 requires covered entities to publish taglines indicating the availability of language assistance services in the top 15 languages of the relevant State or States. Before the effective date of the rule, OCR will make these taglines available electronically in 64 languages; therefore, there will be no burden to the covered entity other than the cost of printing and posting these taglines, as described above with respect to the notice. We are uncertain of the exact volume of taglines that will be printed or posted, but we estimate that covered entities will print and post the same number of taglines as notices and therefore the costs would be comparable to the costs for printing and disseminating the notice, or $3.6 million. The costs to the Federal government for translating the taglines will be approximately $50, based on counting each tagline as being .05 pages long. We estimate that the combined costs of printing and distributing notices, nondiscrimination statements, and taglines will be $7.1 million for entities and $70,400 for the Federal government.

D. Meaningful Access for Individuals With Limited English Proficiency

In the proposed rule, we said that § 92.201, which effectuates Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency, does not pose any new burden on covered entities. This is because, with regard to recipients of Federal financial assistance, the proposed rule adopted recipients' existing obligations under Title VI to take reasonable steps to provide meaningful access to individuals with limited English proficiency and codified the standards consistent with long-standing principles from the HHS LEP Guidance regarding the provision of oral interpretation and written translation services. However, we anticipate that, as a result of issuance of the final rule, covered entities may choose to take one extra step: To develop and implement a language access plan, in order to ensure that they provide meaningful access to individuals with limited English proficiency. We have thus revised our cost estimates, for the final rule, as shown below, to reflect our assumption that 50% of the covered entities will choose to develop a language access plan.

Although Title VI does not apply to the Department, Executive Order 13166 "Improving Access to Services for Persons with Limited English Proficiency" has applied to HHS for nearly 15 years.[329] This Executive Order requires Federal departments to develop and implement a plan, consistent with the HHS LEP Guidance, to ensure that persons with limited English proficiency can meaningfully access the Department's programs and activities. HHS adopted a Language Access Plan in 2000, and updated it in 2013, to provide individuals with limited English proficiency meaningful access to HHS-conducted programs and activities, including Federally-facilitated Health Insurance Marketplaces.[330] Because the final rule does not impose duties beyond the Department's existing obligation under the Executive Order, the rule imposes no new burden on the Department.

In order to estimate the costs of developing a language access plan for recipients of Federal financial assistance, we assume that developing a plan requires approximately three hours of medical and health service managers staff time for the first year, and then an average of one hour of medical and health service managers staff time per year to update the plan in subsequent years. We based our assumption of three hours on feedback from covered entities included in our pre-award compliance review program. This program reviews civil rights compliance of 2,000 to 3,000 health care provider applicants for Medicare Part A per year.

The health care providers that receive Medicare Part A funds already have to develop a written language access plan as a requirement of participation in the Medicare Part A program. Thus, we can reduce the number of covered entities from having a new burden of developing a language access plan. CMS reports data on Medicare hospital spending per claim which identifies 3,209 unique hospitals, which suggests that at least 3,209 hospitals participate in Medicare Part A. As discussed previously, Census data reports that there are a total of 3,688 hospital firms in the United States. Census data reports that there are 6,741 establishments associated with these firms, which in turn suggests that at least 47.6% (3,209/6,741) participate in Medicare Part A. Census data also reports that there are 8,623 nursing care facility entities in the United States. For the purpose of this analysis, we assume that 47.6% of hospitals and nursing care facilities participate in Medicare Part A. Applying 47.6% to all hospitals and nursing care facilities, we estimate that 5,861 entities (47.6% × 3,688 hospital entities (firms) + 47.6% × 8,623 nursing care facility entities) covered by this rule participate in Medicare Part A. This implies that 269,141 entities (firms) will potentially make changes and develop a language access plan as a response to the rule. We arrived at the 269,141 number by subtracting the number of entities participating in Medicare Part A (5,861) from the total number of entities (275,002). We estimate that 50% of these entities will make these changes. Taken together, these assumptions imply that the total cost of the development of language access plans will be approximately $36.0 million (269,141 entities × 50% of entities × 3 hours per entity × $89.24 per hour) in the first year and approximately $12.0 million (269,141 entities × 50% of entities × 1 hour per entity × $89.24 per hour) per year in subsequent years.

We received a number of comments stating that developing a language access plan imposes a cost burden on covered entities. We revised the proposed rule to include cost estimates, in this final rule, for the development of language access plans, as outlined in the paragraph above. We also received comments that providing interpreters imposes a heavy burden on covered entities. The obligation to provide interpreters as part of taking reasonable steps to provide meaningful communication with individuals with limited English proficiency has been a requirement under Title VI for many years. As a result of developing a language access plan, a covered entity might find increased efficiencies in providing language assistance services. Another covered entity might incur extra costs for the provision of language assistance services on more occasions. We are unable to estimate at this point how many covered entities will incur extra costs or the extent of such costs or the savings realized in increased efficiencies. We anticipate that the potential increased efficiencies and increased costs may offset each other to some degree. Thus, we do not believe this rule will impose a greater burden regarding the costs of language assistance services than exist under Title VI.

E. Nondiscrimination on the Basis of Sex

Section 1557 prohibits discrimination on the basis of sex in certain health programs and activities. When providing services, including access to facilities, covered entities must provide individuals with equal program access on the basis of sex, and covered entities are required to treat individuals in a manner consistent with their gender identity.

Title IX applies to educational institutions. Therefore, medical schools, nursing programs, and other health education programs were already prohibited from discriminating on the basis of sex prior to the enactment of Section 1557. Under Section 1557 and this regulation, health insurance issuers receiving Federal financial assistance, hospitals, clinics and other health facilities, HHS health programs and activities, and Title I entities, along with the staff and practitioners working in these health programs, are now similarly prohibited from discriminating on the basis of sex.[331] This section discusses the costs associated with the prohibition of discrimination on the basis of sex in the rule, taking into account the existing environment, including legal authorities, that addresses equal access on the basis of sex.

Covered entities that provide or administer health services or health insurance coverage are covered by the prohibition of discrimination on the basis of sex. The costs that we anticipate that covered entities would incur relate to: (1) Training; (2) enforcement; (3) the posting of the notice; (4) the revision of policies and procedures; and (5) some costs associated with changes in discriminatory practices. This section discusses costs related to changes in policy and procedures and potential changes in discriminatory practices.

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[329] Exec. Order No. 13166, 65 FR 50121 (2000).

[330] U.S. Dep't of Health & Human Servs., Language Access Plan, *supra* note 186.

[331] Consistent with OCR's enforcement of other civil rights authorities, the proposed definition of "Federal financial assistance" under the regulation does not include Medicare Part B, which means that physicians receiving only Medicare Part B payments are not covered under the regulation. However, because almost all physicians receive payments from other Department programs such as Medicaid or Medicare meaningful use payments, we believe that there are very few physicians excluded from these provisions. *See supra* pt. I. C. 1.

1. Costs for Entities Providing or Administering Health Services

The rule would not invalidate specialties that focus on men or women, *e.g.*, gynecology, urology, etc. Nor would providers have to fundamentally change the nature of their operations to comply with the regulation. For example, the rule would not require a provider that operates a gynecological practice to add to or change the types of services offered in the practice.

Under the sex discrimination prohibition, however, providers of health services may no longer deny or limit services based on an individual's sex, without a legitimate nondiscriminatory reason. Although a large number of providers may already be subject to state laws or institutional policies that prohibit discrimination on the basis of sex in the provision of health services, the clarification of the prohibition of sex discrimination in this regulation, particularly as it relates to discrimination on the basis of sex stereotyping and gender identity, may be new. We anticipate that a large number of providers may need to develop or revise policies or procedures to incorporate this prohibition. For example, if a hospital or other provider has specific protocols in place for domestic violence victims, but engages that protocol only for women, the provider would have to revise its procedures to require that protocol for all domestic violence victims regardless of sex. A provider specializing in gynecological services that previously declined to provide a medically necessary hysterectomy for a transgender man would have to revise its policy to provide the procedure for transgender individuals in the same manner it provides the procedure for other individuals.

a. Developing or Revising Policies and Procedures

We assume that it will take, on average, three to five hours for a provider to develop or modify policies and procedures concerning sex discrimination. We are selecting four hours, or the midpoint of this range, for our analysis. We further assume that an average of three of the hours will be spent by a mid-level manager equivalent to a front-line supervisor (Occupation code 43–1011), at a cost of $48.84 per hour after adjusting for overhead and benefits, and an average of one hour will be spent by executive staff equivalent to a general and operations manager (Occupation code 11–1021), at a cost of $93.54 per hour after adjusting for overhead and benefits. We further assume that 75% of covered entities will need to develop or modify policies and procedures, given that some proportion of health care providers already prohibit sex discrimination based on State law or institutional policies prohibiting discrimination generally. The total cost for the estimated 206,252 covered entities to make their policies and procedures consistent with the regulatory prohibition on discrimination on the basis of sex is estimated to be approximately $49.5 million, which we assume is divided evenly between the first two years of compliance.

The above estimates of time and number of entities that would have to revise their policies under the regulation is an approximate estimate based on general BLS data. Due to the wide range of types and sizes of covered entities, from complex multi-divisional hospitals to small neighborhood clinics and physician offices, the above estimates of time and number of entities that would have to revise their policies under the regulation is difficult to calculate.

b. Ending Discriminatory Practices

For providers that discriminate on the basis of sex in violation of the rule, some changes in behavior or action would be necessary to come into compliance. We anticipate some change in the patient population for which a particular provider provides care or the extent of services provided. However, the infrastructure and protocols for providing services or treatment are already in place; providers would simply have to start providing those existing services in a nondiscriminatory manner to individuals regardless of sex. For example, a provider could not refuse to treat a patient for a cold or a broken arm based on the patient's gender identity. Similarly, if the provider is accepting new patients, it must accept a new patient request from a transgender individual and cannot decline to accept a transgender individual in favor of a person who is not transgender.

However, the rule does not impose a burden on covered entities with respect to the number of patients treated. The rule does not require a covered entity to change the total number of patients it sees or to treat more patients than it currently accepts. Providers may continue to treat the same number of patients that were accepted prior to the issuance of this final rule, but they must do so in a nondiscriminatory manner. Thus, for example, if a provider is not accepting new patients, the provider does not have to accept a new patient request from a transgender individual. We anticipate that the costs associated with these types of changes would be de minimis.

Moreover, costs associated with administering care or treating a new patient generally would be offset by the reimbursement received by the provider for providing the care, in the same way the provider gets paid for existing care or treatment of patients. Thus, for example, for the hospital or other provider that needs to revise its protocol for domestic violence to require that protocol for all domestic violence victims regardless of sex, rather than just women, there would be little to no net increase in costs for treating men because the hospital or provider would be paid for its services in the same way it is paid to treat women.

2. Costs for Entities Providing or Administering Health Insurance Coverage

The ACA, including Section 1557, changed the health care landscape for millions of people by instituting protections against sex discrimination in the provision of health care and health insurance coverage. Prior to the ACA, it was standard health insurance practice to treat women differently in premium pricing and coverage of benefits,[332] while transgender individuals frequently experienced discrimination when seeking coverage for treatment.[333]

The ACA addresses inequitable treatment by health plans based on sex in multiple ways. The regulations from CMS implementing the ACA prohibit Title I entities [334] and most health insurance issuers [335] from

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[332] *See* Adelle Simmons, Katherine Warren, & Kellyann McClain, U.S. Dep't of Health & Human Servs., Office of the Assistant Sec'y for Planning and Eval., ASPE Issue Brief, The Affordable Care Act: Advancing the Health of Women and Children (Jan. 2015), *https://aspe.hhs.gov/pdf-report/affordable-care-act-advancing-health-women-and-children;* U.S. Dep't of Health & Human Servs., Women and The Affordable Care Act, *http://www.hhs.gov/healthcare/facts-and-features/fact-sheets/women-and-aca/index.html* (last visited May 3, 2016).

[333] *See* Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV (2010), *http://www.lambdalegal.org/publications/when-health-care-isnt-caring.*

[334] 45 CFR 155.120(c)(1)(ii) prohibits a Health Insurance Marketplace℠ from discriminating based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation.

[335] 45 CFR 147.104(e) prohibits health insurance issuers in non-grandfathered individual, small and large group markets from employing benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, gender

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discriminating based on sex, sexual orientation, and gender identity, in addition to other bases. These market-wide provisions are applicable to health insurance issuers both on and off the Health Insurance Marketplace$^{\text{SM}}$, which includes qualified health plan issuers[336] and health insurance issuers providing non-grandfathered coverage in the individual and group markets outside of the Health Insurance Marketplace$^{\text{SM}}$.[337]

In addition, the ACA prohibits many health insurance issuers from charging higher premiums based on sex;[338] failing to provide essential health benefits that greatly impact women, such as maternity care;[339] failing to cover preventive services that are necessary for women's health, such as mammograms;[340] and denying benefits based on pre-existing conditions[341] or health factors,[342] many of which affect women's health, such as a history of a Caesarian section or a history of domestic violence.[343] Thus, health insurance issuers and the Health Insurance Marketplaces have already had to expand access to women and lesbian, gay, bisexual and transgender (LGBT) individuals under these health insurance market reforms, independent of Section 1557. The existence of these other provisions circumscribes cost burdens on Health Insurance Marketplaces and issuers in the ACA-compliant individual and small group markets that are recipients of Federal financial assistance that are imposed by the prohibition of sex discrimination in the rule.

Section 92.207 (Nondiscrimination in health insurance and other health coverage) of the rule prohibits discrimination on the basis of sex by a covered entity providing or administering health insurance or other health coverage. As noted, many of the same covered entities subject to Section 1557, including Health Insurance Marketplaces and health insurance issuers in the individual and small group markets that are recipients of Federal financial assistance, are also subject to existing nondiscrimination provisions in CMS regulations. Although the CMS regulations complement and do not replace Section 1557 or this part, the existing nondiscrimination requirements applicable to health insurance issuers and Health Insurance Marketplaces have made these entities aware that they are not permitted to discriminate on the basis of sex, sexual orientation, or gender identity, and thus they are familiar with their nondiscrimination obligations under the law. We assume that these covered entities have already taken steps to comply with CMS regulations and so instituted changes in their policies and actions. To the extent these existing obligations overlap with Section 1557 and covered entities have complied with the CMS regulations that prohibit discrimination on the basis of sex, sexual orientation, and gender identity, this rule will impose little or no burden on health insurance issuers and Title I entities to comply with Section 1557's and this part's prohibition on sex discrimination. However, the rule nonetheless imposes some costs.

a. Developing or Revising Policies and Procedures

There may be some incremental burden on issuers and Title I entities in terms of the additional guidance that this rule provides related to sex discrimination, because, in some circumstances, it provides more detail than CMS regulations or guidance. Therefore, covered entities may have an increased burden when incorporating this rule into their existing nondiscrimination policies and procedures. For example, this rule specifies that a categorical coverage exclusion or limitation for all health care services related to gender transition is discriminatory on its face. If a covered entity had not previously understood sex discrimination on the basis of gender identity in this way, the covered entity would have to revise its policies and procedures to provide coverage consistent with this final rule's parameters, which might include revising policies to include gender transition-related care.

However, we note that the number of major U.S. employers providing transgender-inclusive health care coverage has been increasing, from 0 in 2002, to 49 in 2009, 278 in 2013, 336 in 2014, 418 in 2015, and at least 511 in 2016.[344] This indicates that plans that offer transgender-inclusive health care are becoming readily available as models for issuers that may not offer such care, limiting their costs in developing or revising policies and procedures for compliance.

Similar to the estimate for providers of health services, we assume that it will take, on average, three to five hours for issuers of health insurance coverage to develop or modify policies and procedures concerning sex discrimination. We are selecting four hours, or the midpoint of this range, for our analysis. We further assume that three of the hours will be spent by a mid-level manager, at a salary, with fringe benefits and overhead of $57.60 per hour,[345] and one hour will be spent by executive staff, at a salary, with fringe benefits and overhead of $122.15 per hour. Based on our best estimate of industry compliance with CMS regulations, we further assume that one-third or 33% of health insurance issuers will need to develop or modify policies and procedures. Based on an unduplicated count of issuers, we previously identified 180 issuers in the Marketplaces (including Federally-facilitated Marketplaces). One third of this number equals 60 issuers that we estimate would need to revise policies to address the prohibition of sex discrimination in this regulation. The costs to issuers to revise policies and procedures to provide coverage consistent with this rule's parameters equal 60 issuers multiplied by $295 for a one-time cost of $17,700.

b. Ending Discriminatory Practices

In addition to the cost some covered health insurance providers may have for revising policies and procedures to comply with the rule, such providers may also incur a de minimis cost related to the cost of coverage. In this regard, we note that the April 2012 California

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identity, sexual orientation, expected length of life, degree of medical dependency, quality of life, or other health conditions. 45 CFR 156.200(e) prohibits a qualified health plan issuer from discriminating on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation. 45 CFR 156.125(a) prohibits issuers that provide essential health benefits from using benefit designs that discriminate based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. 45 CFR 156.125(b) requires issuers that provide essential health benefits to comply with 45 CFR 156.200(e).

[336] 45 CFR 147.104(e), 156.200(e) and 156.125(a)–(b) are applicable to qualified health plan issuers.

[337] 45 CFR 147.104(e) is applicable to non-grandfathered coverage in the individual, small and large group markets. 45 CFR 147.150(a) incorporates essential health benefits requirements (and implementing regulations at 45 CFR 156.200(e) and 156.125(a)–(b)) for non-grandfathered coverage in the individual and small group markets.

[338] 42 U.S.C.300gg.

[339] *Id.* 18022 (b).

[340] *Id.* 300gg–13 (a)(4).

[341] *Id.* 18001.

[342] *Id.* 300gg–4.

[343] *Id.* 300gg–4(a)(7); ASPE Issue Brief, *supra* note 332.

[344] Human Rights Campaign, Corporate Equality Index, *Rating American Workplaces on Lesbian, Gay, Bisexual and Transgender Equality, http://www.hrc.org/campaigns/corporate-equality-index* (last visited May 3, 2016).

[345] U.S. Dep't of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2015 National Occupational Employment and Wage Estimates by ownership, *http://www.bls.gov/oes/2014/may/oes_nat.htm* (last visited May 3, 2016) (using data for First-Line Supervisors of Office and Administrative Support Workers and General and Operations Managers for the health insurance industry).

Department of Insurance Economic Impact Assessment on Gender Nondiscrimination in Health Insurance found that covering transgender individuals under California's private and public health insurance plans would have an "insignificant and immaterial" impact on costs.[346] This conclusion was based on evidence of low utilization and the estimated number of transgender individuals in California. The transgender population of California was estimated to range between 0.0022% and 0.0173%.[347] The study revealed that, contrary to common assumptions, not all transgender individuals seek surgical intervention, and that gender-confirming health care differs according to the needs and pre-existing conditions of each individual.[348] Despite expecting a possible spike in demand for benefits due to former or current unmet demand, the California Insurance Department concluded that any increased utilization that might occur over time is likely to be so low that any resulting costs remain actuarially immaterial.[349] Additionally, issuers in California that established premium surcharges after enactment of California's Gender Nondiscrimination in Health Insurance Law subsequently eliminated them because they found they did not spend the extra funds generated.[350]

Two other studies also support the conclusion that the cost is de minimis for entities providing or administering health insurance coverage to come into compliance with this rule's provision of nondiscrimination on the basis of sex. One is a 2013 Williams Institute study of 34 public and private employers, and the second consists of cost projections of providing transition-related health-care benefits to members of the military.

The first of these two studies, a 2013 study of 34 employers that provided nondiscriminatory health care coverage, found that providing transition-related benefits to treat gender dysphoria had "zero to very low costs."[351]

The second study, published in the *New England Journal of Medicine,* projected that the cost for providing transition-related health care benefits to members of the military would result in an annual increase of 0.012% of health care costs, "little more than a rounding error in the military's $47.8 billion annual health care budget."[352] Based on the California and two other studies discussed above, we estimate that providing transgender individuals nondiscriminatory insurance coverage and treatment will impact a very small segment of the population due to the fact that the number of transgender individuals (and particularly those who seek surgical procedures in connection with their gender transition) in the general population is small, and consequently will have de minimis impact on the overall cost of care and on health insurance premiums.[353]

F. Accessibility of Electronic and Information Technology

Although Section 1557 requires covered entities to ensure that the health programs, services, and activities provided through electronic and information technology are accessible to individuals with disabilities, all covered entities affected by Section 1557 already have these obligations under Section 508, Section 504 or the ADA.

1. HHS Health Programs and Activities, Including the Federally-Facilitated Marketplaces

Section 508 requires that electronic and information technology developed, procured, maintained, or used by Federal agencies be accessible for individuals with disabilities (both members of the public and Federal employees). Section 504 also establishes general obligations for Federal agencies to make their programs that are provided through electronic and information technology accessible to individuals with disabilities. Both Section 504 and Section 508 were in place before the passage of the ACA. There is, therefore, no additional burden under Section 1557 for HHS health programs, including the Federally-facilitated Marketplaces, as the Section 1557 requirements are consistent with the obligations these programs already have under Section 504 and Section 508.

2. Recipients of Federal Financial Assistance From HHS and Title I Entities

Section 504 also establishes general obligations for entities receiving Federal financial assistance to make their programs, services, and activities provided through electronic and information technology accessible to individuals with disabilities. The ADA imposes similar accessibility requirements on covered entities. This rule thus imposes no additional burden on recipients of Federal financial assistance from HHS because Section 1557 is consistent with existing standards these entities are already obligated to meet under the ADA and Section 504. Title I entities have no Section 1557 burden with respect to this proposed requirement, as the Title I entities must already be compliant with the ADA, which is consistent with the Section 1557 accessibility standards.

G. Enforcing the Rule

After grievances are filed with covered entities or complaints are filed with OCR, there are associated costs to investigate and resolve those grievances and complaints. We believe the following costs result from enforcement of the Section 1557 regulation:

- Costs to covered entities for modifying and implementing grievance procedures to cover grievances filed under Section 1557.
- Costs to OCR for reviewing and investigating complaints, monitoring corrective action plans, and taking other enforcement actions against covered entities.

In the analysis below, we estimate the aggregate costs of these enforcement procedures, and analyze the costs to covered entities separately from the costs to OCR.

1. Costs to Covered Entities

Federal civil rights laws that were in place before the enactment of Section 1557 apply to entities that receive Federal financial assistance. Entities subject to those laws are already required to have in place established grievance procedures to address complaints of disability discrimination and complaints of sex discrimination in education programs. We anticipated that additional costs arising from the expansion of the grievance process to cover all bases included in Section 1557, including race, color, national origin, and age, as well as sex discrimination in health care, could impose additional costs on covered entities. We assumed a slight increase in the number of grievances filed, and a corresponding increase in time to investigate and resolve these additional grievances.

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[346] State of Cal., Dep't of Ins., Economic Impact Assessment Gender Nondiscrimination in Health Insurance. (Apr. 13, 2012). *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[347] *Id.*

[348] *Id.* at 8.

[349] *Id.* at 9.

[350] *Id.* at 6–7.

[351] The Williams Inst., Cost and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans: Findings from a Survey of Employers, at 2 (Sept. 2013), *http://williamsinstitute.law.ucla.edu/wp-content/uploads/Herman-Cost-Benefit-of-Trans-Health-Benefits-Sept-2013.pdf*

[352] A. Belkin, "Caring for Our Transgender Troops — The Negligible Cost of Transition-Related Care," 373 New Eng. J. Med. 1089 (Sept. 15, 2015).

[353] State of Cal., Dep't of Ins., *supra* note 346, at 2, 5. Issuers in California that established a premium surcharge to cover the City of San Francisco's expected claim costs eventually eliminated the additional premium because they found their cost assumptions were 15 times higher than actual claims generated.

To compute the anticipated costs for covered entities to enforce the regulation, we looked to OCR data. The current number of civil rights complaints filed annually with OCR is approximately 3,000. Since the passage of Section 1557, OCR's complaint workload has increased slightly, with approximately 15 to 20 unique Section 1557 cases filed each year. If we include another ten cases per year as a result of the promulgation of the regulation, we calculate an increase of 30 cases per year or 1% of the annual caseload of 3,000. We assume the incremental workload will be similar for affected entities and thus will be approximately 1%. We anticipate that within the first five years following the promulgation of the regulation, complaints will initially increase, but then will eventually drop off as covered entities modify their policies and practices in response to the rule. Due to the likelihood that applicable changes will need to be phased in, we assume one half of the annual projected costs for investigating discrimination complaints will be incurred during the first year and three quarters of the annual projected enforcement costs will be spent in the second year and the full amounts in the third through fifth years. Although we have data on OCR's caseload, we have no data on the caseload of affected covered entities.

We assume that as a result of promulgating the regulation, the 41,250 covered entities with 15 or more employees will require an average of an additional 1% of a Full Time Equivalent (FTE) for designated grievance officials to investigate discrimination grievances in years three through five following publication of the final rule, with costs half as large in the first year and costs three quarters as large in the second year. We assume the grievance official's salary is equivalent to that of medical and health service managers (occupation code 11–9111), who have annual median wages of $103,680. These assumptions imply costs, after adjusting for fringe benefits and overhead, of $42.8 million in the first year, $64.2 million in the second year, and $85.5 million in years three through five following publication of the final rule.

One comment suggested that litigation costs may also rise as a result of issuance. We assume that the costs of litigation are included in the costs listed in the paragraph above.

The same incremental calculations apply to the workloads of State agencies and the officials working in these agencies. If we assume the same increases in workload at each State agency as discussed previously, and the average mid-level State official salary is $94,580 (including fringe benefits and overhead), we must multiply $94,580 by the number of State covered entities.[354] To arrive at the number of State covered entities we make the following assumptions:

- We assume that there are 56 Medicaid State agencies;
- We assume that there are 56 State health departments;
- We assume that there are 1,003 State and local government community hospitals;[355] and
- We assume that each of 3,143 counties has a county health department that provides direct health services (*e.g.*, immunization clinics) and is accountable to the State Health Department. We assume that each of the county health departments has a designated official for handling grievances.

The total number of State covered entities is 4,252. Multiplying $94,580 by 4,252 equals $402.2 million. One percent of this value equals $4.0 million. This implies costs of $2.0 million in the first year, $3.0 million in the second year and $4.0 million in subsequent years following the publication of the final rule.

2. Costs to OCR

We considered the various OCR enforcement costs together, based on OCR average salary data presented in its annual budgets. According to the FY 2016 President's Budget, $28,400,000 and 137 FTEs were requested for Enforcement and Regional Operations, at a cost of approximately $201,000 per FTE. Of the 137 FTEs, approximately 40 FTEs spend 100% of their investigative time enforcing the civil rights laws.[356] If we make the same assumption we did above and assume the same increase in caseload from the issuance of Section 1557 as discussed above, the anticipated increase in number of staff necessary would be approximately 0.4 of an FTE (1% of 40) and would cost approximately $40,200 in the first year, $60,300 in the second year, and $80,400 in subsequent years following the publication of the final rule.

3. Summary of Cost and Phase-In

The table below summarizes the costs attributable to the regulation that covered entities may incur following enactment of the final regulation. We assume that half of the training costs and changes to policies and procedures on the prohibition of discrimination on the basis of sex will be incurred in the first year and the second half will be expended in the second year. For covered entities that will be printing and distributing notices to their patients and policy holders, we assume that all of the estimated printing and distribution costs will be expended in the first year after the effective date of the rule. Familiarization costs, information collection requirements and paperwork burden costs would be incurred within the first year after the effective date of the final regulation. Cost of enforcement, by contrast, will increase over the course of the first five years.

TABLE 5—COST SUMMARY OF THE REGULATION FOLLOWING ENACTMENT OF THIS FINAL RULE

[Discounted 3% and 7% in millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total/ annualized
Training and Familiarization (undiscounted)	234.9	185.8	0.0	0.0	0.0	420.8
Training and Familiarization (3%)	228.1	175.2	0.0	0.0	0.0	88.1
Training and Familiarization (7%)	219.6	162.3	0.0	0.0	0.0	93.1
Enforcement (undiscounted)	44.8	67.2	89.6	89.6	89.6	381.0
Enforcement (3%)	43.5	63.4	82.0	79.6	77.3	75.5
Enforcement (7%)	41.9	58.7	73.2	68.4	63.9	74.6
Notice Publication (undiscounted)	7.2	0.0	0.0	0.0	0.0	7.2

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[354] Based on the annual salary of Executive Secretary and Executive Administrative Assistant.

[355] American Hospital Ass'n: Fast Facts on US Hospitals, (Jan. 2016), *http://www.aha.org/research/rc/stat-studies/101207fastfacts.pdf.*

[356] This is based on an informal staff estimate.

TABLE 5—COST SUMMARY OF THE REGULATION FOLLOWING ENACTMENT OF THIS FINAL RULE—Continued

[Discounted 3% and 7% in millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total/ annualized
Notice Publication (3%)	7.0	0.0	0.0	0.0	0.0	1.5
Notice Publication (7%)	6.7	0.0	0.0	0.0	0.0	1.6
Sex discrimination	24.8	24.8	0.0	0.0	0.0	49.5
Policy and Procedure Changes (undiscounted):						
Sex discrimination	24.0	23.3	0.0	0.0	0.0	10.3
Policy and Procedure Changes (3%):						
Sex discrimination	23.1	21.6	0.0	0.0	0.0	10.9
Policy and Procedure Changes (7%):						
Language Access Plan (undiscounted)	36.0	12.0	12.0	12.0	12.0	84.1
Language Access Plan (3%)	35.0	11.3	11.0	10.7	10.4	17.1
Language Access Plan (7%)	33.7	10.5	9.8	9.2	8.6	17.5
Total (undiscounted)	347.7	289.8	101.6	101.6	101.6	942.5
Total (3%)	337.6	273.2	93.0	90.3	87.7	192.5
Total (7%)	325.0	253.2	83.0	77.5	72.5	197.8

Note: Discounted and annualized values take into account the cost of borrowing and paying back funds at hypothetical interest rates to simulate opportunity costs.

This completes our analysis of the costs of the final rule. Next, we examine the benefits that can be expected to accrue as a result of the final rule.

III. Benefits & Transfers

In enacting Section 1557 of the ACA, Congress recognized the benefits of equal access to health services and health insurance that all individuals should have, regardless of their race, color, national origin, age, or disability. Section 1557 brought together the rights to equal access that had been guaranteed under Title VI, the Age Act and Section 504. At the same time, Congress extended these protections and rights to individuals seeking access to health services and health insurance without discrimination on the basis of sex.

This rule implements the provisions of Section 1557. In most respects, the rule clarifies existing obligations under existing authorities, and we have noted in the cost analysis that we do not expect that covered entities will incur costs related to the clarification of those existing obligations in the final rule. As the HHS LEP Guidance[357] and regulation implementing Title VI[358] indicate, recipients are already required to take reasonable steps to ensure meaningful access to their programs and activities by persons with limited English proficiency. We note that the additional provisions related to serving individuals with limited English proficiency in the final rule may create some additional costs but will also create substantial benefits to patients and providers by improving access to quality care.[359]

Studies show that individuals with limited English proficiency experience barriers to receiving regular and adequate health care. However, according to the Institute of Medicine, when reliable language assistance services are utilized, patients experience treatment-related benefits, such as enhanced understanding of physician instruction, shared decision-making, provision of informed consent, adherence with medication regimes, preventive testing, appointment attendance, and follow-up compliance.[360] Additional intangible benefits may include retention of cultural information, exchange of information, greater satisfaction with care,[361] and enhanced privacy and autonomy of individuals with limited English proficiency who may have previously had to rely on family members for language assistance.[362]

Health service providers also benefit from providing language assistance services for individuals with limited English proficiency. Providers can more confidently make diagnoses, prescribe medications, reach treatment decisions, and ensure that treatment plans are understood by patients.[363] "Language is also an important tool for clinicians to establish an empathic connection with patients[;]" accordingly, language assistance services benefit both patients and providers alike.[364] One study states that ensuring effective communication can also help providers avoid costs associated with "damages paid to patients, legal fees, the time lost when defending a lawsuit, the loss of reputation and patients, the fear of possible monetary loss, and the stress and distraction of litigation."[365] Another study of malpractice claims found that a malpractice carrier insuring in four states paid over $2 million in damages or settlements as well as over $2 million in legal fees over a four year period for claims arising from failure to use an appropriate interpreter.[366]

We have also noted that we expect that the prohibition of sex discrimination in the final rule will generate certain actions and other changes in behavior by covered entities and that these actions and changes will impose costs. These actions and other changes in behavior will also result in benefits.

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[357] 68 FR 47311, 47313 (Aug. 8, 2003).

[358] 45 CFR 80.3.

[359] Report to Congress. Assessment of the Total Benefits and Costs of Implementing Executive Order No. 13166: Improving Access to Services for Persons with Limited English Proficiency (Mar. 2002), p. 20, *https://www.justice.gov/sites/default/files/crt/legacy/2010/12/14/omb-lepreport.pdf.*

[360] Brian D. Smedley, Adrienne Y. Stith, Alan R. Nelson, eds., Institute of Medicine, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care, Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, Board on Health Science Policy,* (2003), pp.142, 191; Report to Congress, *supra* note 359 at 20–22.

[361] *Id.*

[362] Kelvin Quan & Jessica Lynch, *The High Costs of Language Barriers in Medical Malpractice* (2010), p.17, *http://www.healthlaw.org/images/stories/High_Costs_of_Language_Barriers_in_Malpractice.pdf.*

[363] ASPE, *Caring for Immigrants: Health Care Safety Nets in Los Angeles, New York, Miami and Houston,* (2001), *https://aspe.hhs.gov/execsum/caring-immigrants-health-care-safety-nets-los-angeles-new-york-miami-and-houston;* Elizabeth A. Jacobs, Donald S. Shepard, Jose A. Suaya and Esta-Lee Stone, *Overcoming Language Barriers in Health Care: Costs and Benefits of Interpreter Services, Am. J. Public Health (2004), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448350/;* Unequal Treatment, *supra* note 360 at 141.

[364] *Unequal Treatment, supra* note 360 at 141.

[365] *The High Costs of Language Barriers in Medical Malpractice, supra* note 362 at 15.

[366] Agency for Healthcare Research and Quality, Improving Patient Safety Systems for Patients With Limited English Proficiency: A Guide for Hospitals (2012), *http://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf.*

The provisions prohibiting sex discrimination in the ACA increase the affordability and accessibility of health care for women and transgender individuals. However, despite the ACA improving access to health services and health insurance, many women and transgender individuals continue to experience discrimination in the health care context, which can lead to denials of adequate health care and increases in existing health disparities in underserved communities. This continued discrimination demonstrates the need for further clarification regarding the prohibition of discrimination on the basis of sex.

Prior to the enactment of the ACA, insurance companies were allowed to impose higher premiums on women or deny women coverage altogether. If issuers did cover women, they frequently did not cover a number of women's health services, including routine preventive services, such as pap smears or mammograms. Insurance premiums previously could differ by sex, and were often higher for females relative to males. The ACA prohibits differential treatment based on sex, includes maternity coverage in essential health benefits, and requires non-grandfathered plans to cover women's preventive services without copays, among other benefits.

For transgender individuals, a major barrier to receiving care is a concern over being refused medical treatment based on bias against them.[367] In a 2010 report, 26.7% of transgender respondents reported that they were refused needed health care.[368] A 2011 survey revealed that 25% of transgender individuals reported being subject to harassment in medical settings, and 50% reported having to teach their medical providers about transgender care.[369] We received many comments expressing anecdotal evidence of these statistics.

Another potential barrier for transgender individuals to care is covered entities' nondiscrimination policies, which often do not include gender identity. The 2014 Human Rights Campaign Healthcare Equality Index, which evaluates health care facilities' LGBT policies and practices, found that among the 640 hospitals it evaluated, 501 had patient nondiscrimination policies but of those only 257 had a patient nondiscrimination policy that included both the terms "sexual orientation" and "gender identity." [370]

Yet another barrier to care for transgender individuals is the process of obtaining health insurance coverage. A study by the Center for American Progress found that transgender individuals have often experienced difficulties when seeking insurance coverage.[371] Similarly, in 2014, Out2Enroll, a national campaign that serves as a key link between LGBT communities and the ACA by connecting LGBT people with information about their new coverage options, issued findings in a report entitled *"Key Lessons for LGBT Outreach and Enrollment under the Affordable Care Act."* [372] The report focuses on the lack of adequate training of Navigator staff when encountering LGBT individuals seeking access to the Health Insurance Marketplaces. A major complaint was that Navigator staff was unaware of the multitude of discriminatory practices and policy restrictions in which issuers engage to deny or restrict coverage of transgender individuals, and that Navigator staff lacked basic knowledge of health issues that are unique to transgender individuals.[373]

Ultimately, transgender individuals who have experienced discrimination in the health care context often postpone or do not seek needed health care, which may lead to negative health consequences.[374] A study by the National Center for Transgender Equality and the National Gay and Lesbian Task Force found that "one-quarter of the more than 6,400 transgender and gender-nonconforming respondents reported . . . being denied needed treatment[,] . . . being harassed in health care settings[,] . . . [and] postponing medical care because of discrimination by providers." [375] We received several comments echoing these statements, both from individuals citing personal experiences and from entities citing data. This kind of discrimination exacerbates health disparities experienced by the LGBT population, including: higher rates of mental health issues, including depression and suicide attempts; higher risk of HIV/AIDS; higher use of tobacco and other drugs; and higher risk of certain cancers, such as breast cancer, with some portion of the differential potentially attributable to barriers to health care.[376]

By prohibiting discrimination on the basis of sex, Section 1557 would result in more women and transgender individuals obtaining coverage and accessing health services. Since 2013, the uninsured rate for women has declined, with nearly 9.5 million women gaining health coverage as of 2016.[377] Similarly, uninsured rates for LGBT individuals dropped from 34% in 2013 to 26% in 2014.[378] While these declines in the rates of the uninsured are attributable to many factors, among these factors may be provisions in the ACA prohibiting discriminatory practices in insurance. We expect that the Section 1557 regulation may contribute to a continued reduction in the number of individuals who are uninsured, although the reduction would be much more modest.

For a representative example, we look to a State of California economic impact assessment of State practices prohibiting gender discrimination in health care, which cites the following benefits: [379]

1. Reduced violence against affected individuals;

2. Reduced depression and suicide attempts among the affected population; and

3. Overall declines in substance abuse, smoking and alcohol abuse rates, and improvements in mental health among treated individuals in LGBT populations who receive appropriate medical treatment.

Moreover, because discrimination contributes to health disparities, the prohibition of sex discrimination in health care under Section 1557 can help reduce health disparities. While it is not possible to quantify the benefits of the reduction in health disparities, the benefits would include more people receiving adequate health care, regardless of their sex, including gender identity.

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[367] Lambda Legal, *supra* note 333 at 12–13.

[368] *Id.* at 10.

[369] National Center for Transgender Equality and National Gay and Lesbian Task Force, Injustice at Every Turn: A Report of the National Transgender Discrimination Survey, 5–6 (2011), *http://www.thetaskforce.org/.*

[370] Human Rights Campaign, Healthcare Equality Index 2014, *http://www.hrc.org/reports/hei.*

[371] Laura E. Durso, Kellan Baker, and Andrew Cray, Center for American Progress Issue Brief: LGBT Communities and the Affordable Care Act Findings from a National Survey, (Oct. 10, 2013), *http://www.preventionjustice.org/wp-content/uploads/2013/10/CAP–LGBT-Messaging-Research.pdf.*

[372] Out2Enroll, Key Lessons for LGBT Outreach and Enrollment under the Affordable Care Act (July 24, 2014), *http://out2enroll.org/lgbthealthcare/wp-content/uploads/2014/07/O2E_KeyLessons_FINAL.pdf.*

[373] *Id.* at 24.

[374] Kellan E, Baker, Center for American Progress, Open Doors for All, Sexual Orientation and Gender Identity Protections in Health Care (Apr. 30, 2015), *https://www.americanprogress.org/issues/lgbt/report/2015/04/30/112169/open-doors-for-all/.*

[375] *Id.*

[376] *Id.*

[377] U.S. Dep't of Health & Human Servs., Office of the Assistant Secretary for Planning and Eval., ASPE Issue Brief: Health Insurance Coverage and the Affordable Care Act 201–2016, 2 (Mar. 3, 2016) *https://aspe/hhs.gov.*

[378] Kellan Baker, Laura E. Durso, and Andrew Cray, Center for American Progress, Moving the Needle, The Impact of the Affordable Care Act on LGBT Communities, 3 (Nov. 2014), *https://www.americanprogress.org/issues/lgbt/report/2014/11/17/101575/moving-the-needle/.*

[379] California Department of Insurance, *supra* note 346, at 10–12.

The health and longevity benefits discussed above as potential effects of this rule assume additional or higher-quality medical services are provided to affected individuals. These services would be associated with costs (which we lack data to estimate). As mentioned in the earlier discussion of actuarial risk, to the extent that changes in insurance premiums do not alter how society uses its resources, the final rule would result in transfers between members of society, rather than social costs or benefits. In addition to women and transgender individuals, health service providers and the Federal government could also be recipients of these transfers. For example, in 2013, $53.3 billion was paid to offset uncompensated care, of which the Federal government paid for approximately $32.8 billion.[380] Based on estimated coverage gains in 2014, uncompensated care costs are expected to continue to fall substantially following continued major insurance coverage expansions, including coverage expansions through the Health Insurance Marketplace℠.[381] While issuance of the Section 1557 regulation is not a factor in this projection, we believe that the Section 1557 regulation will likewise contribute to a decrease in payments by the Federal government for uncompensated care by promoting an increase in the number of individuals who have coverage when they receive care.

Aside from the specific benefits and transfers that women and transgender individuals, and the health care community can be expected to gain from the enactment of the regulation, there are additional benefits that are intangible and unquantifiable that derive from providing equal access to health care for all.

IV. Alternatives Considered

In the course of developing this regulation, OCR considered various alternatives. Some of those alternatives are discussed in the preamble. A discussion of alternatives cannot cover all alternatives considered by OCR. The following alternatives are meant to be a representative sample to show how burden reduction was a major consideration in constructing the standards in this regulation.

The first option is no new regulatory action. We did not select this option because we believe the regulation provides substantial benefits to society, net of the costs. We received a comment suggesting that we consider either writing a more informative than prescriptive regulation or delaying the regulation, based on a possible trend of increased voluntary compliance by health care agencies with nondiscrimination statutes. OCR's current experience, however, points to the importance of and need for a prescriptive regulation. OCR provides education and information on the civil rights statutes and regulations, conducts technical assistance and outreach to promote compliance, and is developing training materials to provide information and technical assistance on this rule. However, OCR has found that providing information and outreach is not sufficient to ensure nondiscrimination in health care programs and activities. OCR continues to receive and resolve many complaints of discrimination and to hear of ongoing discrimination through outreach and communications with stakeholders. The regulation will inform stakeholders of their rights so that affected individuals know that they can seek OCR's assistance, and will provide clarity for covered entities, limiting uncertainty and promoting compliance. In addition, the majority of the comments from the public in response to the proposed rule favored issuance of a regulation.

OCR considered requiring covered entities to provide separate notices, covering separate content, *e.g.*, separate notices on the requirements concerning the provision of meaningful access for individuals with limited English proficiency, requirements concerning effective communication for individuals with disabilities, and policies on nondiscrimination. To reduce the burden on covered entities, OCR rejected this option in favor of a comprehensive single-notice requirement. We are also permitting entities to combine the Section 1557 notice with other notices that the entities may be required to post.

OCR decided to further reduce the burden imposed on covered entities by the notice requirement by making available a sample notice, located in Appendix A. OCR allows covered entities flexibility in complying with the notice requirement by giving covered entities the option of using the sample notice or developing their own notice. Although OCR considered requiring covered entities to post the notice in 15 languages (Spanish (or Spanish Creole), Chinese, Vietnamese, Korean, Tagalog, Russian, Arabic, French Creole, French (including Patois, Cajun), Portuguese (or Portuguese Creole), Polish, Japanese, Italian, German, and Persian (Farsi)), we rejected that option. Instead, we are providing the notice translated into 64 languages, and are allowing covered entities the discretion to post one or more of the translated notices. We believe that making translated notices readily available to covered entities maximizes efficiency and economies of scale, provides flexibility while minimizing burden, and helps provide greater access for beneficiaries and consumers. Additionally, although OCR considered requiring covered entities to create their own taglines in the top 15 national languages spoken by individuals with limited English proficiency, we rejected that option. Instead, OCR is making available to covered entities the taglines in 64 languages. As the tagline requirement for the covered entities only requires the cost of printing and posting, this burden is expected to be minimal.

OCR considered not providing training materials to covered entities on the requirements of the regulation. However, in order to reduce costs and burden, OCR is providing these materials, which will reduce covered entities' costs of developing training materials from $500 per entity to $125 per entity, resulting in a savings of approximately $104 million. Entities are assumed to bear one quarter of the total costs. These costs result from paying the presenters who will run the training sessions, providing classroom space, and supplementing the training materials that OCR is making available (should they choose to do so).

OCR considered remaining silent on covered entities' obligations to comply with Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency. We rejected this approach because we were concerned that OCR's silence would create ambiguity about covered entities' obligations to individuals with limited English proficiency and could jeopardize the access of individuals with limited

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[380] Teresa A. Coughlin, John Holahan, Kyle Caswell, and Megan McGrath, The Henry J. Kaiser Family Foundation, Uncompensated Care for the Uninsured in 2013: A Detailed Examination (May 30, 2014), p. 4. *https://kaiserfamilyfoundation.files.wordpress.com/2014/05/8596-uncompensated-care-for-the-uninsured-in-2013.pdf.*

[381] U.S. Dep't of Health & Human Servs., Office of the Assistant Sec'y for Planning and Eval., Thomas DeLeire, Karen Joynt, and Ruth McDonald, ASPE Issue Brief, Impact of Insurance Expansion on Hospital Uncompensated Care Costs in 2014 (Sept. 24, 2015) *https://aspe.hhs.gov/sites/default/files/pdf/77061/ib_UncompensatedCare.pdf.*

English proficiency to covered entities' health programs and activities. Clearly explaining the standards also promotes compliance and reduces enforcement costs. Options for addressing the prohibition of national origin discrimination as it affects individuals with limited English proficiency are discussed in the preamble to the proposed rule.

OCR considered a regulatory scheme requiring covered entities to provide meaningful access to each individual with limited English proficiency by providing effective language assistance services, at no cost, unless such action would result in an undue burden or fundamental alteration. OCR also considered requiring covered entities of a certain type or size to have enhanced obligations to provide language assistance services. Such enhanced obligations would include providing a predetermined range of language assistance services in certain non-English languages that met defined thresholds. A covered entity that was not of a certain type or size still would be required to provide meaningful access to each individual with limited English proficiency in its health programs and activities, but the covered entity would not have to provide a predetermined range of language assistance services in certain non-English languages. OCR also explored applying the threshold requirement to standardized vital documents on a national, State, or county level, as well as specific to a covered entity's geographic service area.

The strengths of these alternate regulatory schemes included limited obligations for small businesses providing health programs or activities and defined standards for larger entities. The costs of these approaches included the complexity of the regulatory scheme and the potential burden on the covered entities of a certain type or size that would have enhanced applications. OCR determined these costs outweigh the benefits.

OCR considered drafting new provisions addressing effective communication (apart from communication through electronic and information technology) with individuals with disabilities, but instead is incorporating provisions of the regulation implementing Title II of the ADA to ensure consistency for covered entities and potentially reduce burden by limiting resources spent on training and modification of policies and procedures.

Options regarding communication through electronic and information technology are discussed in the preamble to the regulation. Regarding the accessibility requirements under the proposed regulation, OCR at first considered a narrower interpretation that the rule applied only to access to health programs and activities provided through covered entities' Web sites. However, we chose a broader interpretation, to include both Web sites and other means of electronic and information technology. While this could potentially increase the burden on recipients of Federal financial assistance and State-based Marketplaces, this would offer clarity to covered entities, increase the benefit of the rule, and help enhance access for individuals with disabilities.

In the area of compliance, OCR considered having one set of procedures for all compliance activities involving recipients of Federal financial assistance and State-based Marketplace^{SM} entities. Instead, OCR decided to adopt the unique Age Act procedures [382] for age-related compliance activities under Section 1557 because Age Act compliance activities and Section 1557 compliance activities regarding age discrimination are likely to substantially overlap.

With regard to other areas of compliance, OCR considered developing a separate set of procedures for Section 1557 compliance activities involving HHS health programs and activities, but decided to largely adopt the existing procedures for disability compliance activities involving HHS health programs and activities (with some enhancement) to improve efficiencies for OCR and the HHS health programs and activities covered by Section 1557.

V. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that includes a Federal mandate that could result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold level is approximately $146 million.

The Unfunded Mandates Reform Act does not address the total cost of a final rule. Rather, it focuses on certain categories of cost, mainly those "Federal mandate" costs resulting from: (1) Imposing enforceable duties on State, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

Our impact analysis shows that burden associated with training staff working for covered entities will be spread widely across health care entities, State and local governmental entities, and a substantial number of health insurance issuers. The analysis estimates the unfunded burden will be about $422 million in training and familiarization costs. We project that for the first few years following promulgation of the final rule, private sector costs for investigating discrimination complaints may amount to $87 million per year. Within the first five years following the final rule's promulgation, we anticipate complaints will increase, and then eventually drop off as covered entities modify their policies and practices in response to the final rule.

As we explain in the RIA, we believe there will be benefits gained from the promulgation of this regulation in the form of reduction in discrimination based on race, color, national origin, sex, age, and disability, and the corresponding improvement in the quality of care to underserved communities. In response to comments concerning the costs to covered entities, we note that we have not included some changes that would have been beneficial to individuals because we recognize that they would be costly for covered entities.

VI. Executive Order 13132: Federalism

As required by Executive Order 13132 [383] on Federalism, OCR examined the effects of provisions in the regulation on the relationship between the Federal government and the States. OCR has concluded that the regulation does have Federalism implications but preempts State law only where the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.

The regulation attempts to balance State autonomy with the necessity of creating a Federal floor that will provide a uniform level of nondiscrimination protection across the country. The regulation restricts regulatory preemption of State law to the minimum level necessary to achieve the objectives of the underlying Federal statute, Section 1557 of the ACA.

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[382] The Age Act procedures, for example, require mediation of all age discrimination complaints, and exhaustion of administrative remedies prior to the filing of a civil lawsuit. 45 CFR 91.43, 91.50.

[383] Exec. Order No. 13132, 64 FR 43255 (1999).

It is recognized that the States generally have laws that relate to nondiscrimination against individuals on a variety of bases. State laws continue to be enforceable, unless they prevent application of the final rule. The final rule explicitly provides that it is not to be construed to supersede State or local laws that provide additional protections against discrimination on any basis articulated under the regulation. Provisions of State law relating to nondiscrimination that is "more stringent" than the proposed Federal regulatory requirements or implementation specifications will continue to be enforceable.

Section 3(b) of Executive Order 13132 recognizes that national action limiting the policymaking discretion of States will be imposed only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance. Discrimination issues in relation to health care are of national concern by virtue of the scope of interstate health commerce. The ACA's provisions reflect this position.

Section 3(d)(2) of Executive Order 13132 requires that where possible, the Federal government defer to the States to establish standards. Title I of the ACA authorized the Secretary to promulgate regulations to implement Section 1557, and we have done so accordingly.

Section 4(a) of Executive Order 13132 expressly contemplates preemption when there is a conflict between exercising State and Federal authority under a Federal statute. Section 4(b) of the Executive Order authorizes preemption of State law in the Federal rulemaking context when "the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute." The approach in this regulation is consistent with these standards in the Executive Order in superseding State authority only when such authority is inconsistent with standards established pursuant to the grant of Federal authority under the statute.

Section 6(b) of Executive Order 13132 includes some qualitative discussion of substantial direct compliance costs that State and local governments could incur as a result of a proposed regulation. We have determined that the costs of the final rule will not impose substantial direct compliance costs on State or local governments. We have considered the cost burden that this rule will impose on State and local health care and benefit programs, and estimate State and local government costs will be in the order of $17.8 million in the first two years of implementation. The $17.8 million represents the sum of the costs of training State workers and enforcement costs attributable to State agencies analyzed above.

VII. Regulatory Flexibility Act (RFA)

The RFA requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule will have a significant impact on a substantial number of small entities. The RFA generally defines a "small entity" as:

(1) A proprietary firm meeting the size standards of the Small Business Administration (SBA);

(2) A nonprofit organization that is not dominant in its field; or

(3) A small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of "small entity").

HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3% for 5% or more of affected small entities.

In instances where OCR judged that the final rule would have a significant impact on a substantial number of small entities, we considered alternatives to reduce the burden. To accomplish our task, we first identified all the small entities that may be impacted, and then evaluated whether the economic burden we determined in the RIA represents a significant economic impact.

A. Entities That Will Be Affected

HHS has traditionally classified most health care providers as small entities even though some nonprofit providers would not meet the definition of "small entity" were they proprietary firms. Nonprofit entities are small if they are independently owned and operated and are not dominant in their fields.

The CMS Provider of Service file has indicators for profit and nonprofit entities, but these have proven to be unreliable. The Census data identifies firms' tax status by profit and non-profit status but only reports revenues and does not report them by the profit and non-profit status of the entity.

1. Physicians

One class of providers we do not automatically classify as small businesses is physician practices. Physician practices are businesses and therefore are "small" if they meet the SBA's definition. The current size standard for physicians (excluding mental health specialists) (North American Industry Classification System code 62111) is annual receipts of less than $11 million.[384] Using the Census data showing the number of firms, employees and payroll, we selected physicians that reported fewer than 20 employees as the top end for small physician offices. This equaled 17,835 entities or 9.6% of all physician offices defined as "large." This left 167,814 offices or 90.4% as "small."[385]

2. Pharmacies

Pharmacies also are businesses, and the size standard for them is annual receipts of less than $27.5 million. According to Census Statistics of U.S. Businesses, there are 18,852 pharmacy and drug store firms (North American Industry Classification System code 44611). Because of the lack of revenue or receipt data for pharmacies, we are unable to estimate the number of small pharmacies based on the SBA size standard. However, using the number of employees taken from the Statistics of U.S. Businesses as a proxy for revenues, the data is divided by number of employees per firm and shows the number of employers with fewer than 20 employees and those with more than 20 employees.[386] The number of firms with fewer than 20 employees is 16,520 and represents 88% of the total number of pharmacy firms. It seemed reasonable to assume that firms with fewer than 20 employees satisfy the SBA size standard and thus we accepted that the number of small pharmacy firms equaled 16,520. As with the number of small physician offices, our method can only identify the minimum number of "small" pharmacies that meet the SBA size standard. We cannot determine the actual number of "small" pharmacies.

3. Health Insurance Issuers

Another class of covered entities that are business enterprises is health insurance issuers. The SBA size standard for health insurance issuers is annual receipts of $38.5 million. Although the Blue Cross/Blue Shield companies that operate in some markets are organized as nonprofit entities, they often are large enough so as to not meet the definition of "small entity."

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[384] U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes. Small Business Administration, (June, 2016), *https://www.sba.gov/sites/default/files/Size5FStandards5FTable.pdf.*

[385] Physician practices may earn more than $11 million per year and that would reduce the number of "large" practices to be excluded from the analysis. But as we will later show, large practices will have proportionally larger workforce staff that must be excluded from the analysis.

[386] U.S. Census Bureau, Statistics of U.S. Businesses, *supra* note 314.

Unfortunately, we cannot use the Census revenue data for estimating the number of small health insurance issuers because the Census data combines life and health insurance. Substituting costs for revenues allows us to obtain a rough estimate of the number of large insurance issuers, realizing that cost will probably be less than revenues, thus giving us a lower count of large issuers. Using the National Health Expenditure for 2013, net cost of health insurance equaled $173.6 billion. However, the 2012 Census data report a total of 815 health insurance issuers. Dividing the $174 billion in costs by the number of insurance issuers reported in the census tables yields average costs of over $213 million, which means that average annual revenues per issuer exceeds $213 million. We concluded, therefore, that there are almost no small insurance issuers. The above analysis comports with the conclusion CMS published in the Health Insurance Web Portal Requirements.[387]

4. Local Government Entities

We also excluded local governmental entities from our count of small entities because we lack the data to classify them by populations of fewer than 50,000. The following table shows the number of small covered entities we estimated could be affected by the proposed rule.

TABLE 6—SMALL COVERED ENTITIES

NAIC	Entity type	Number of firms
62142	Outpatient mental health and substance abuse centers	4,987
62141	HMO medical centers	104
62142	Kidney dialysis centers	492
62143	Freestanding ambulatory surgical and emergency centers	4,121
621498	All other outpatient care centers	5,399
6215	Medical and diagnostic laboratories	7,958
6216	Home health care services	21,668
6219	All other ambulatory health care services	6,956
62321	Residential mental retardation facilities	6,225
62199	General medical and surgical hospitals	3,067
621991	Psychiatric and substance abuse hospitals	411
6221	Specialty (except psychiatric and substance abuse) hospitals	373
6231	Nursing care facilities (skilled nursing facilities)	8,623
44611	Pharmacies and drug stores	16,520
6211	Offices of physicians	167,814
	Navigator grantees	100
	Total small entities	254,998

B. Whether the Rule Will Have a Significant Economic Impact on Covered Small Entities

Total undiscounted costs associated with the final rule are an average of $189 million per year over a five year period. If all of those costs are borne by small entities, this amounts to an average of $739 each year over that five year period. As a result, we believe that fewer than 5% of all small entities will experience a burden of greater than 3% of their revenues. Ambulatory health care services facilities (North American Industry Classification System 621), for example, are small entities with an average of 13 employees and revenue of $1.7 million based on 2012 reported data for employees of 6.4 million and total revenues of $825.7 million for 485,235 firms.[388] In addition, the majority of the costs associated with this final rule are proportional to the size of entities, meaning that even the smallest of the affected entities are unlikely to face a substantial impact. Thus, we would not consider this regulation a significant burden on a substantial number of small entities, and, therefore, the Secretary certifies that the final rule will not have a significant impact on a substantial number of small entities.

VIII. Conclusion

For the most part, because this regulation is consistent with existing standards applicable to the covered entities, the new burdens created by its issuance are minimal. The major impacts are in the areas of voluntary training, posting of notices, enforcement (where increased caseloads pose incremental costs on covered entities), voluntary development of language access plans, and revisions or development of new policies and procedures. The final rule does not include broad expansions of existing civil rights requirements on covered entities, and therefore minimizes the imposition of new burdens. Nevertheless, it is still a major rule with economically significant costs. The annualized cost of this rule over the first five years following its publication is $192.5 million using a discount rate of 3%, and $197.8 million using a discount rate of 7%. This RIA was organized and designed to explain the origin of these cost impacts and to incorporate relevant public comments.

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[387] 75 CFR 24481, May 5, 2010.

[388] U.S. Dep't of Labor, Bureau of Labor Statistics, Industries at a Glance, *http://www.bls.gov/iag/tgs/iag621.htm* (last visited Mar. 26, 2016).

TABLE 7—ACCOUNTING STATEMENT

Accounting statement				
Category	Primary estimate	Low estimate	High estimate	Source
BENEFITS				
Qualitative Benefits (02)	• Potential health improvements and longevity extensions as a result of reduced barriers to medical care for transgender individuals.		....	RIA
COSTS (millions)				
Annualized monetized	Covered entities train 40% of their employees on the new regulations	Covered entities train 60% of their employees on the new regulations	....	
3%	192.5	177.0	208.1	RIA
7%	197.8	181.4	214.2	RIA
Non-quantified costs (02)	Costs of increased provision of health care services as a result of reduced barriers to access for transgender individuals.		....	RIA
Transfers (02)	Health insurance premium reductions for affected women, with offsetting increases for other premium payers in affected plans.		....	RIA
Effects on State and Local Governments (02)	$17.8 million costs in the first 2 years (training + enforcement)		....	RIA
Effects on Small Entities (02)	Average of less than $1,000 per small entity per year		....	RFA

List of Subjects in 45 CFR Part 92

Administrative practice and procedure, Civil rights, Discrimination, Elderly, Health care, Health facilities, Health insurance, Health programs and activities, Individuals with disabilities, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination.

For the reasons set forth in the preamble, the Department of Health and Human Services adds 45 CFR part 92 as follows:

PART 92—NONDISCRIMINATION ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AGE, OR DISABILITY IN HEALTH PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE AND HEALTH PROGRAMS OR ACTIVITIES ADMINISTERED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OR ENTITIES ESTABLISHED UNDER TITLE I OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

Subpart A—General Provisions

92.1 Purpose and effective date.
92.2 Application.
92.3 Relationship to other laws.
92.4 Definitions.
92.5 Assurances required.
92.6 Remedial action and voluntary action.
92.7 Designation of responsible employee and adoption of grievance procedures.
92.8 Notice requirement.

Subpart B—Nondiscrimination Provisions

92.101 Discrimination prohibited.

Subpart C—Specific Applications to Health Programs and Activities

92.201 Meaningful access for individuals with limited English proficiency.
92.202 Effective communication for individuals with disabilities.
92.203 Accessibility standards for buildings and facilities.
92.204 Accessibility of electronic and information technology.
92.205 Requirement to make reasonable modifications.
92.206 Equal program access on the basis of sex.
92.207 Nondiscrimination in health-related insurance and other health-related coverage.
92.208 Employer liability for discrimination in employee health benefit programs.
92.209 Nondiscrimination on the basis of association.

Subpart D—Procedures

92.301 Enforcement mechanisms.
92.302 Procedures for health programs and activities conducted by recipients and State-based Marketplaces.
92.303 Procedures for health programs and activities administered by the Department.
Appendix A to Part 92—Sample Notice Informing Individuals About Nondiscrimination and Accessibility

Requirements and Sample Nondiscrimination Statement
Appendix B to Part 92—Sample Tagline Informing Individuals With Limited English Proficiency of Language Assistance Services
Appendix C to Part 92—Sample Section 1557 of the Affordable Care Act Grievance Procedure

Authority: 42 U.S.C. 18116, 5 U.S.C. 301.

Subpart A—General Provisions

§ 92.1 Purpose and effective date.

The purpose of this part is to implement Section 1557 of the Patient Protection and Affordable Care Act (ACA) (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. Section 1557 provides that, except as provided in Title I of the ACA, an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or Section 504 of the Rehabilitation Act of 1973, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the ACA. This part applies to health programs or activities administered by recipients of Federal financial assistance from the Department, Title I entities that administer health programs or activities, and Department-administered health programs or activities. The effective date of this part shall be July 18, 2016, except to the extent that provisions of this part require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

§ 92.2 Application.

(a) Except as provided otherwise in this part, this part applies to every health program or activity, any part of which receives Federal financial assistance provided or made available by the Department; every health program or activity administered by the Department; and every health program or activity administered by a Title I entity.

(b)(1) Exclusions to the application of the Age Discrimination Act of 1975, as set forth at 45 CFR 91.3(b)(1), apply to claims of discrimination based on age under Section 1557 or this part.

(2) Insofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required.

(c) Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 92.3 Relationship to other laws.

(a) *Rule of interpretation.* Neither Section 1557 nor this part shall be construed to apply a lesser standard for the protection of individuals from discrimination than the standards applied under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, or the regulations issued pursuant to those laws.

(b) *Other laws.* Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals under Title VI of the Civil Rights Act of 1964, Title VII of the Civil Rights Act of 1964, the Architectural Barriers Act of 1968, Title IX of the Education Amendments of 1972, Sections 504 or 508 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, the Americans with Disabilities Act of 1990, as amended by the Americans with Disabilities Act Amendments Act of 2008, or other Federal laws or to supersede State or local laws that provide additional protections against discrimination on any basis described in § 92.1.

§ 92.4 Definitions.

As used in this part, the term—

1991 Standards means the 1991 ADA Standards for Accessible Design, published at Appendix A to 28 CFR part 36 on July 26, 1991, and republished as Appendix D to 28 CFR part 36 on September 15, 2010.

2010 Standards means the 2010 ADA Standards for Accessible Design, as defined at 28 CFR 35.104.

ACA means the Patient Protection and Affordable Care Act (Pub. L. 111–148, 124 Stat. 119 (2010) as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111–152, 124 Stat. 1029 (codified in scattered sections of U.S.C.)).

ADA means the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*), as amended.

Age means how old an individual is, or the number of elapsed years from the date of an individual's birth.

Age Act means the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), as amended.

Applicant means an individual who applies to participate in a health program or activity.

Auxiliary aids and services include:

(1) Qualified interpreters on-site or through video remote interpreting (VRI) services, as defined in 28 CFR 35.104 and 36.303(b); note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunication products and systems, text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible electronic and information technology; or other effective methods of making aurally delivered information available to individuals who are deaf or hard of hearing;

(2) Qualified readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs; large print materials; accessible electronic and information technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision;

(3) Acquisition or modification of equipment and devices; and

(4) Other similar services and actions.

Covered entity means:

(1) An entity that operates a health program or activity, any part of which receives Federal financial assistance;

(2) An entity established under Title I of the ACA that administers a health program or activity; and

(3) The Department.

Department means the U.S. Department of Health and Human Services.

Director means the Director of the Office for Civil Rights (OCR) of the Department.

Disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment, as defined and construed in the Rehabilitation Act, 29 U.S.C. 705(9)(B), which incorporates the definition of disability in the ADA, 42 U.S.C. 12102, as amended. Where this part cross-references regulatory provisions that use the term "handicap," "handicap" means "disability" as defined in this section.

Electronic and information technology means the same as "electronic and information technology," or any term that replaces "electronic and information technology," as it is defined in 36 CFR 1194.4.

Employee health benefit program means:

(1) Health benefits coverage or health insurance coverage provided to employees and/or their dependents established, operated, sponsored or administered by, for, or on behalf of one or more employers, whether provided or administered by entities including but not limited to an employer, group health plan (as defined in the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1191b(a)(1)), third party administrator, or health insurance issuer.

(2) An employer-provided or employer-sponsored wellness program;

(3) An employer-provided health clinic; or

(4) Long term care coverage or insurance provided or administered by an employer, group health plan, third party administrator, or health insurance issuer for the benefit of an employer's employees.

Federal financial assistance. (1) Federal financial assistance means any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or any other arrangement by which the Federal government provides or otherwise makes available assistance in the form of:

(i) Funds;

(ii) Services of Federal personnel; or

(iii) Real and personal property or any interest in or use of such property, including:

(A) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(B) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal government.

(2) Federal financial assistance the Department provides or otherwise makes available includes Federal financial assistance that the Department plays a role in providing or administering, including all tax credits under Title I of the ACA, as well as payments, subsidies, or other funds extended by the Department to any entity providing health-related insurance coverage for payment to or on behalf of an individual obtaining health-related insurance coverage from that entity or extended by the Department directly to such individual for payment to any entity providing health-related insurance coverage.

Federally-facilitated Marketplace^{SM} means the same as "Federally-facilitated Exchange" defined in 45 CFR 155.20.

Gender identity means an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual's sex assigned at birth. The way an individual expresses gender identity is frequently called "gender expression," and may or may not conform to social stereotypes associated with a particular gender. A transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth.

Health Insurance Marketplace^{SM} means the same as "Exchange" defined in 45 CFR 155.20.

Health program or activity means the provision or administration of health-related services, health-related insurance coverage, or other health-related coverage, and the provision of assistance to individuals in obtaining health-related services or health-related insurance coverage. For an entity principally engaged in providing or administering health services or health insurance coverage or other health coverage, all of its operations are considered part of the health program or activity, except as specifically set forth otherwise in this part. Such entities include a hospital, health clinic, group health plan, health insurance issuer, physician's practice, community health center, nursing facility, residential or community-based treatment facility, or other similar entity. A health program or activity also includes all of the operations of a State Medicaid program, a Children's Health Insurance Program, and the Basic Health Program.

HHS means the U.S. Department of Health and Human Services.

Individual with a disability means any individual who has a disability as defined for the purpose of Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 705(20)(B)–(F), as amended. Where this part cross-references regulatory provisions applicable to a "handicapped individual," "handicapped individual" means "individual with a disability" as defined in this section.

Individual with limited English proficiency means an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English.

Language assistance services may include, but are not limited to:

(1) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for an individual with limited English proficiency, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency;

(2) Written translation, performed by a qualified translator, of written content in paper or electronic form into languages other than English; and

(3) Taglines.

National origin includes, but is not limited to, an individual's, or his or her ancestor's, place of origin (such as country or world region) or an individual's manifestation of the physical, cultural, or linguistic characteristics of a national origin group.

On the basis of sex includes, but is not limited to, discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity.

Qualified bilingual/multilingual staff means a member of a covered entity's workforce who is designated by the covered entity to provide oral language assistance as part of the individual's current, assigned job responsibilities and who has demonstrated to the covered entity that he or she:

(1) Is proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology, and

(2) is able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.

Qualified individual with a disability means, with respect to a health program or activity, an individual with a disability who, with or without reasonable modifications to policies, practices, or procedures, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of aids, benefits, or services offered or provided by the health program or activity.

Qualified interpreter for an individual with a disability. (1) A qualified interpreter for an individual with a disability means an interpreter who via a remote interpreting service or an on-site appearance:

(i) Adheres to generally accepted interpreter ethics principles, including client confidentiality; and

(ii) is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary, terminology and phraseology.

(2) For an individual with a disability, qualified interpreters can include, for example, sign language interpreters, oral transliterators (individuals who represent or spell in the characters of another alphabet), and cued language transliterators (individuals who represent or spell by using a small number of handshapes).

Qualified interpreter for an individual with limited English proficiency means an interpreter who via a remote interpreting service or an on-site appearance:

(1) Adheres to generally accepted interpreter ethics principles, including client confidentiality;

(2) has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language; and

(3) is able to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

Qualified translator means a translator who:

(1) Adheres to generally accepted translator ethics principles, including client confidentiality;

(2) has demonstrated proficiency in writing and understanding both written English and at least one other written non-English language; and

(3) is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

Recipient means any State or its political subdivision, or any instrumentality of a State or its political subdivision, any public or private agency, institution, or organization, or other entity, or any individual, to whom Federal financial assistance is extended directly or through another recipient and which operates a health program or activity, including any subunit, successor, assignee, or transferee of a recipient.

Section 504 means Section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112; 29 U.S.C. 794), as amended.

Section 1557 means Section 1557 of the ACA (42 U.S.C. 18116).

Sex stereotypes means stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. These stereotypes can include the expectation that individuals will consistently identify with only one gender and that they will act in conformity with the gender-related expressions stereotypically associated with that gender. Sex stereotypes also include gendered expectations related to the appropriate roles of a certain sex.

State-based Marketplace ^SM^ means a Health Insurance Marketplace ^SM^ established by a State pursuant to 45 CFR 155.100 and approved by the Department pursuant to 45 CFR 155.105.

Taglines mean short statements written in non-English languages that indicate the availability of language assistance services free of charge.

Title I entity means any entity established under Title I of the ACA, including State-based Marketplaces and Federally-facilitated Marketplaces.

Title VI means Title VI of the Civil Rights Act of 1964 (Pub. L. 88–352; 42 U.S.C. 2000d *et seq.*), as amended.

Title IX means Title IX of the Education Amendments of 1972 (Pub. L. 92–318; 20 U.S.C. 1681 *et seq.*), as amended.

§ 92.5 Assurances required.

(a) *Assurances.* An entity applying for Federal financial assistance to which this part applies shall, as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director, that the entity's health programs and activities will be operated in compliance with Section 1557 and this part. A health insurance issuer seeking certification to participate in a Health Insurance Marketplace ^{SM} or a State seeking approval to operate a State-based Marketplace ^{SM} to which Section 1557 or this part applies shall, as a condition of certification or approval, submit an assurance, on a form specified by the Director, that the health program or activity will be operated in compliance with Section 1557 and this part. An applicant or entity may incorporate this assurance by reference in subsequent applications to the Department for Federal financial assistance or requests for certification to participate in a Health Insurance Marketplace ^{SM} or approval to operate a State-based Marketplace ^{SM}.

(b) *Duration of obligation.* The duration of the assurances required by this subpart is the same as the duration of the assurances required in the Department's regulations implementing Section 504, 45 CFR 84.5(b).

(c) *Covenants.* When Federal financial assistance is provided in the form of real property or interest, the same conditions apply as those contained in the Department's regulations implementing Section 504, at 45 CFR 84.5(c), except that the nondiscrimination obligation applies to discrimination on all bases covered under Section 1557 and this part.

§ 92.6 Remedial action and voluntary action.

(a) *Remedial action.* (1) If the Director finds that a recipient or State-based Marketplace ^{SM} has discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of Section 1557 or this part, such recipient or State-based Marketplace ^{SM} shall take such remedial action as the Director may require to overcome the effects of the discrimination.

(2) Where a recipient is found to have discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of Section 1557 or this part, and where another recipient exercises control over the recipient that has discriminated, the Director, where appropriate, may require either or both entities to take remedial action.

(3) The Director may, where necessary to overcome the effects of discrimination in violation of Section 1557 or this part, require a recipient or State-based Marketplace ^{SM} to take remedial action with respect to:

(i) Individuals who are no longer participants in the recipient's or State-based Marketplace ^{SM}'s health program or activity but who were participants in the health program or activity when such discrimination occurred; or

(ii) Individuals who would have been participants in the health program or activity had the discrimination not occurred.

(b) *Voluntary action.* A covered entity may take steps, in addition to any action that is required by Section 1557 or this part, to overcome the effects of conditions that result or resulted in limited participation in the covered entity's health programs or activities by individuals on the basis of race, color, national origin, sex, age, or disability.

§ 92.7 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* Each covered entity that employs 15 or more persons shall designate at least one employee to coordinate its efforts to comply with and carry out its responsibilities under Section 1557 and this part, including the investigation of any grievance communicated to it alleging noncompliance with Section 1557 or this part or alleging any action that would be prohibited by Section 1557 or this part. For the Department, including the Federally-facilitated Marketplaces, the Director will be deemed the responsible employee under this section.

(b) *Adoption of grievance procedures.* Each covered entity that employs 15 or more persons shall adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557 or this part. For the Department, including the Federally-facilitated Marketplaces, the procedures for addressing complaints of discrimination on the grounds covered under Section 1557 or this part will be deemed grievance procedures under this section.

§ 92.8 Notice requirement.

(a) Each covered entity shall take appropriate initial and continuing steps to notify beneficiaries, enrollees, applicants, and members of the public of the following:

(1) The covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities;

(2) The covered entity provides appropriate auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, free of charge and in a timely manner, when such aids and services are necessary to ensure an equal opportunity to participate to individuals with disabilities;

(3) The covered entity provides language assistance services, including translated documents and oral interpretation, free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with limited English proficiency;

(4) How to obtain the aids and services in paragraphs (a)(2) and (3) of this section;

(5) An identification of, and contact information for, the responsible employee designated pursuant to § 92.7(a), if applicable;

(6) The availability of the grievance procedure and how to file a grievance, pursuant to § 92.7(b), if applicable; and

(7) How to file a discrimination complaint with OCR in the Department.

(b) Within 90 days of the effective date of this part, each covered entity shall:

(1) As described in paragraph (f)(1) of this section, post a notice that conveys the information in paragraphs (a)(1) through (7) of this section; and

(2) As described in paragraph (g)(1) of this section, if applicable, post a nondiscrimination statement that conveys the information in paragraph (a)(1) of this section.

(c) For use by covered entities, the Director shall make available, electronically and in any other manner that the Director determines appropriate, the content of a sample notice that conveys the information in paragraphs (a)(1) through (7) of this section, and the content of a sample nondiscrimination statement that conveys the information in paragraph (a)(1) of this section, in English and in the languages triggered by the obligation in paragraph (d)(1) of this section.

(d) Within 90 days of the effective date of this part, each covered entity shall:

(1) As described in paragraph (f)(1) of this section, post taglines in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States; and

(2) As described in paragraph (g)(2) of this section, if applicable, post taglines in at least the top two languages spoken by individuals with limited English proficiency of the relevant State or States.

(e) For use by covered entities, the Director shall make available, electronically and in any other manner that the Director determines appropriate, taglines in the languages triggered by the obligation in paragraph (d)(1) of this section.

(f)(1) Each covered entity shall post the notice required by paragraph (a) of this section and the taglines required by paragraph (d)(1) of this section in a conspicuously-visible font size:

(i) In significant publications and significant communications targeted to beneficiaries, enrollees, applicants, and members of the public, except for significant publications and significant communications that are small-sized, such as postcards and tri-fold brochures;

(ii) In conspicuous physical locations where the entity interacts with the public; and

(iii) In a conspicuous location on the covered entity's Web site accessible from the home page of the covered entity's Web site.

(2) A covered entity may also post the notice and taglines in additional publications and communications.

(g) Each covered entity shall post, in a conspicuously-visible font size, in significant publications and significant communications that are small-sized, such as postcards and tri-fold brochures:

(1) The nondiscrimination statement required by paragraph (b)(2) of this section; and

(2) The taglines required by paragraph (d)(2) of this section.

(h) A covered entity may combine the content of the notice required in paragraph (a) of this section with the content of other notices if the combined notice clearly informs individuals of their civil rights under Section 1557 and this part.

Subpart B—Nondiscrimination Provisions

§ 92.101 Discrimination prohibited.

(a) *General.* (1) Except as provided in Title I of the ACA, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which this part applies.

(2) This part does not apply to employment, except as provided in § 92.208.

(b) *Specific discriminatory actions prohibited.* Under any health program or activity to which this part applies:

(1)(i) Each covered entity must comply with the regulation implementing Title VI, at § 80.3(b)(1) through (6) of this subchapter.

(ii) No covered entity shall, on the basis of race, color, or national origin, aid or perpetuate discrimination against any person by providing significant assistance to any entity or person that discriminates on the basis of race, color, or national origin in providing any aid, benefit, or service to beneficiaries of the covered entity's health program or activity.

(2)(i) Each recipient and State-based Marketplace^{SM} must comply with the regulation implementing Section 504, at §§ 84.4(b), 84.21 through 84.23(b), 84.31, 84.34, 84.37, 84.38, and 84.41 through 84.52(c) and 84.53 through 84.55 of this subchapter. Where this paragraph cross-references regulatory provisions that use the term "recipient," the term "recipient or State-based Marketplace^{SM}" shall apply in its place.

(ii) The Department, including the Federally-facilitated Marketplaces, must comply with the regulation implementing Section 504, at §§ 85.21(b), 85.41 through 85.42, and 85.44 through 85.51 of this subchapter.

(3)(i) Each covered entity must comply with the regulation implementing Title IX, at § 86.31(b)(1) through (8) of this subchapter. Where this paragraph cross-references regulatory provisions that use the term "student," "employee," or "applicant," these terms shall be replaced with "individual."

(ii) A covered entity may not, directly or through contractual or other arrangements, utilize criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program with respect to individuals on the basis of sex.

(iii) In determining the site or location of a facility, a covered entity may not make selections that have the effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any programs to which this regulation applies, on the basis of sex; or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity on the basis of sex.

(iv) A covered entity may operate a sex-specific health program or activity (a health program or activity that is restricted to members of one sex) only if the covered entity can demonstrate an exceedingly persuasive justification, that is, that the sex-specific health program or activity is substantially related to the achievement of an important health-related or scientific objective.

(4)(i) Each covered entity must comply with the regulation implementing the Age Act, at § 91.11(b) of this subchapter.

(ii) No covered entity shall, on the basis of age, aid or perpetuate discrimination against any person by providing significant assistance to any agency, organization, or person that discriminates on the basis of age in providing any aid, benefit, or service to beneficiaries of the covered entity's health program or activity.

(5) The enumeration of specific forms of discrimination in this paragraph does not limit the generality of the prohibition in paragraph (a) of this section.

(c) The exceptions applicable to Title VI apply to discrimination on the basis of race, color, or national origin under this part. The exceptions applicable to Section 504 apply to discrimination on the basis of disability under this part. The exceptions applicable to the Age Act apply to discrimination on the basis of age under this part. These provisions are found at §§ 80.3(d), 84.4(c), 85.21(c), 91.12, 91.15, and 91.17–.18 of this subchapter.

(d) Where the regulatory provisions referenced in paragraphs (b)(1), (b)(3), and (b)(4), and paragraph (c) of this section use the term "recipient," the term "covered entity" shall apply in its place. Where the regulatory provisions referenced in paragraphs (b)(1), (b)(3), and (b)(4) and paragraph (c) of this section use the terms "program or activity" or "program" or "education program," the term "health program or activity" shall apply in their place.

Subpart C—Specific Applications to Health Programs and Activities

§ 92.201 Meaningful access for individuals with limited English proficiency.

(a) *General requirement.* A covered entity shall take reasonable steps to provide meaningful access to each individual with limited English proficiency eligible to be served or likely to be encountered in its health programs and activities.

(b) *Evaluation of compliance.* In evaluating whether a covered entity has met its obligation under paragraph (a) of this section, the Director shall:

(1) Evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, to the individual with limited English proficiency; and

(2) Take into account other relevant factors, including whether a covered entity has developed and implemented an effective written language access plan, that is appropriate to its particular circumstances, to be prepared to meet its obligations in § 92.201(a).

(c) *Language assistance services requirements.* Language assistance services required under paragraph (a) of this section must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency.

(d) *Specific requirements for interpreter and translation services.* Subject to paragraph (a) of this section:

(1) A covered entity shall offer a qualified interpreter to an individual with limited English proficiency when oral interpretation is a reasonable step to provide meaningful access for that individual with limited English proficiency; and

(2) A covered entity shall use a qualified translator when translating written content in paper or electronic form.

(e) *Restricted use of certain persons to interpret or facilitate communication.* A covered entity shall not:

(1) Require an individual with limited English proficiency to provide his or her own interpreter;

(2) Rely on an adult accompanying an individual with limited English proficiency to interpret or facilitate communication, except:

(i) In an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available; or

(ii) Where the individual with limited English proficiency specifically requests that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances;

(3) Rely on a minor child to interpret or facilitate communication, except in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available; or

(4) Rely on staff other than qualified bilingual/multilingual staff to communicate directly with individuals with limited English proficiency.

(f) *Video remote interpreting services.* A covered entity that provides a qualified interpreter for an individual with limited English proficiency through video remote interpreting services in the covered entity's health programs and activities shall provide:

(1) Real-time, full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;

(2) A sharply delineated image that is large enough to display the interpreter's

face and the participating individual's face regardless of the individual's body position;

(3) A clear, audible transmission of voices; and

(4) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the video remote interpreting.

(g) *Acceptance of language assistance services is not required.* Nothing in this section shall be construed to require an individual with limited English proficiency to accept language assistance services.

§ 92.202 Effective communication for individuals with disabilities.

(a) A covered entity shall take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in health programs and activities, in accordance with the standards found at 28 CFR 35.160 through 35.164. Where the regulatory provisions referenced in this section use the term "public entity," the term "covered entity" shall apply in its place.

(b) A recipient or State-based Marketplace^{SM} shall provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

§ 92.203 Accessibility standards for buildings and facilities.

(a) Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace^{SM} shall comply with the 2010 Standards as defined in § 92.4, if the construction or alteration was commenced on or after July 18, 2016, except that if a facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace^{SM}, was not covered by the 2010 Standards prior to July 18, 2016, such facility or part of a facility shall comply with the 2010 Standards, as defined in § 92.4, if the construction was commenced after January 18, 2018. Departures from particular technical and scoping requirements by the use of other methods are permitted where substantially equivalent or greater access to and usability of the facility is provided. All newly constructed or altered buildings or facilities subject to this section shall comply with the requirements for a "public building or facility" as defined in Section 106.5 of the 2010 Standards.

(b) Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace^{SM} in conformance with the 1991 Standards or the 2010 Standards as defined in § 92.4 shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction or alteration was commenced on or before July 18, 2016. Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace^{SM} in conformance with the Uniform Federal Accessibility Standards as defined in § 92.4, shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction was commenced before July 18, 2016 and such facility was not covered by the 1991 Standards or 2010 Standards.

§ 92.204 Accessibility of electronic and information technology.

(a) Covered entities shall ensure that their health programs or activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities. When undue financial and administrative burdens or a fundamental alteration exist, the covered entity shall provide information in a format other than an electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology.

(b) Recipients and State-based Marketplaces shall ensure that their health programs and activities provided through Web sites comply with the requirements of Title II of the ADA.

§ 92.205 Requirement to make reasonable modifications.

A covered entity shall make reasonable modifications to policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. For the purposes of this section, the term "reasonable modifications" shall be interpreted in a manner consistent with the term as set forth in the ADA Title II regulation at 28 CFR 35.130(b)(7).

§ 92.206 Equal program access on the basis of sex.

A covered entity shall provide individuals equal access to its health programs or activities without discrimination on the basis of sex; and a covered entity shall treat individuals consistent with their gender identity, except that a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available.

§ 92.207 Nondiscrimination in health-related insurance and other health-related coverage.

(a) *General.* A covered entity shall not, in providing or administering health-related insurance or other health-related coverage, discriminate on the basis of race, color, national origin, sex, age, or disability.

(b) *Discriminatory actions prohibited.* A covered entity shall not, in providing or administering health-related insurance or other health-related coverage:

(1) Deny, cancel, limit, or refuse to issue or renew a health-related insurance plan or policy or other health-related coverage, or deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, on the basis of race, color, national origin, sex, age, or disability;

(2) Have or implement marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability in a health-related insurance plan or policy, or other health-related coverage;

(3) Deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other

limitations or restrictions on coverage, for any health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that an individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available;

(4) Have or implement a categorical coverage exclusion or limitation for all health services related to gender transition; or

(5) Otherwise deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual.

(c) The enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a) of this section.

(d) Nothing in this section is intended to determine, or restrict a covered entity from determining, whether a particular health service is medically necessary or otherwise meets applicable coverage requirements in any individual case.

§ 92.208 Employer liability for discrimination in employee health benefit programs.

A covered entity that provides an employee health benefit program to its employees and/or their dependents shall be liable for violations of this part in that employee health benefit program only when:

(a) The entity is principally engaged in providing or administering health services, health insurance coverage, or other health coverage;

(b) The entity receives Federal financial assistance a primary objective of which is to fund the entity's employee health benefit program; or

(c) The entity is not principally engaged in providing or administering health services, health insurance coverage, or other health coverage, but operates a health program or activity, which is not an employee health benefit program, that receives Federal financial assistance; except that the entity is liable under this part with regard to the provision or administration of employee health benefits only with respect to the employees in that health program or activity.

§ 92.209 Nondiscrimination on the basis of association.

A covered entity shall not exclude from participation in, deny the benefits of, or otherwise discriminate against an individual or entity in its health programs or activities on the basis of the race, color, national origin, sex, age, or disability of an individual with whom the individual or entity is known or believed to have a relationship or association.

Subpart D—Procedures

§ 92.301 Enforcement mechanisms.

(a) The enforcement mechanisms available for and provided under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, or the Age Discrimination Act of 1975 shall apply for purposes of Section 1557 as implemented by this part.

(b) Compensatory damages for violations of Section 1557 are available in appropriate administrative and judicial actions brought under this rule.

§ 92.302 Procedures for health programs and activities conducted by recipients and State-based Marketplaces.

(a) The procedural provisions applicable to Title VI apply with respect to administrative enforcement actions concerning discrimination on the basis of race, color, national, origin, sex, and disability discrimination under Section 1557 or this part. These procedures are found at §§ 80.6 through 80.11 of this subchapter and part 81 of this subchapter.

(b) The procedural provisions applicable to the Age Act apply with respect to enforcement actions concerning age discrimination under Section 1557 or this part. These procedures are found at §§ 91.41 through 91.50 of this subchapter.

(c) When a recipient fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may find noncompliance with Section 1557 and initiate appropriate enforcement procedures, including beginning the process for fund suspension or termination and taking other action authorized by law.

(d) An individual or entity may bring a civil action to challenge a violation of Section 1557 or this part in a United States District Court in which the recipient or State-based Marketplace℠ is found or transacts business.

§ 92.303 Procedures for health programs and activities administered by the Department.

(a) This section applies to discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities administered by the Department, including the Federally-facilitated Marketplaces.

(b) The procedural provisions applicable to Section 504 at §§ 85.61 through 85.62 of this subchapter shall apply with respect to enforcement actions against the Department concerning discrimination on the basis of race, color, national origin, sex, age, or disability under Section 1557 or this part. Where this section cross-references regulatory provisions that use the term "handicap," the term "race, color, national origin, sex, age, or disability" shall apply in its place.

(c) The Department shall permit access by OCR to its books, records, accounts, other sources of information, and facilities as may be pertinent to ascertain compliance with Section 1557 or this part. Where any information required of the Department is in the exclusive possession of any other agency, institution or individual, and the other agency, institution or individual shall fail or refuse to furnish this information, the Department shall so certify and shall set forth what efforts it has made to obtain the information. Asserted considerations of privacy or confidentiality may not operate to bar OCR from evaluating or seeking to enforce compliance with Section 1557 or this part. Information of a confidential nature obtained in connection with compliance evaluation or enforcement shall not be disclosed except where necessary under the law.

(d) The Department shall not intimidate, threaten, coerce, or discriminate against any individual for the purpose of interfering with any right or privilege secured by Section 1557 or this part, or because such individual has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding or hearing under Section 1557 or this part. The identity of complainants shall be kept confidential by OCR, except to the extent necessary to carry out the purposes of Section 1557 or this part.

Appendix A to Part 92—Sample Notice Informing Individuals About Nondiscrimination and Accessibility Requirements and Sample Nondiscrimination Statement: Discrimination is Against the Law

[Name of covered entity] complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. [Name of covered entity] does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

[Name of covered entity]:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:

  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact [Name of Civil Rights Coordinator]

If you believe that [Name of covered entity] has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: [Name and Title of Civil Rights Coordinator], [Mailing Address], [Telephone number], [TTY number—if covered entity has one], [Fax], [Email]. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, [Name and Title of Civil Rights Coordinator] is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at *https://ocrportal.hhs.gov/ocr/portal/lobby.jsf,* or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–868–1019, 800–537–7697 (TDD).

Complaint forms are available at *http://www.hhs.gov/ocr/office/file/index.html.*

Nondiscrimination statement for significant publications and signification communications that are small-size:

[Name of covered entity] complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.

Appendix B to Part 92—Sample Tagline Informing Individuals With Limited English Proficiency of Language Assistance Services

ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–xxx–xxx–xxxx (TTY: 1–xxx–xxx–xxxx).

Appendix C to Part 92—Sample Section 1557 of the Affordable Care Act Grievance Procedure

It is the policy of [Name of Covered Entity] not to discriminate on the basis of race, color, national origin, sex, age or disability. [Name of Covered Entity] has adopted an internal grievance procedure providing for prompt and equitable resolution of complaints alleging any action prohibited by Section 1557 of the Affordable Care Act (42 U.S.C. 18116) and its implementing regulations at 45 CFR part 92, issued by the U.S. Department of Health and Human Services. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities. Section 1557 and its implementing regulations may be examined in the office of [Name and Title of Section 1557 Coordinator], [Mailing Address], [Telephone number], [TTY number—if covered entity has one], [Fax], [Email], who has been designated to coordinate the efforts of [Name of Covered Entity] to comply with Section 1557.

Any person who believes someone has been subjected to discrimination on the basis of race, color, national origin, sex, age or disability may file a grievance under this procedure. It is against the law for [Name of Covered Entity] to retaliate against anyone who opposes discrimination, files a grievance, or participates in the investigation of a grievance.

Procedure:

- Grievances must be submitted to the Section 1557 Coordinator within (60 days) of the date the person filing the grievance becomes aware of the alleged discriminatory action.
- A complaint must be in writing, containing the name and address of the person filing it. The complaint must state the problem or action alleged to be discriminatory and the remedy or relief sought.
- The Section 1557 Coordinator (or her/his designee) shall conduct an investigation of the complaint. This investigation may be informal, but it will be thorough, affording all interested persons an opportunity to submit evidence relevant to the complaint. The Section 1557 Coordinator will maintain the files and records of [Name of Covered Entity] relating to such grievances. To the extent possible, and in accordance with applicable law, the Section 1557 Coordinator will take appropriate steps to preserve the confidentiality of files and records relating to grievances and will share them only with those who have a need to know.
- The Section 1557 Coordinator will issue a written decision on the grievance, based on a preponderance of the evidence, no later than 30 days after its filing, including a notice to the complainant of their right to pursue further administrative or legal remedies.
- The person filing the grievance may appeal the decision of the Section 1557 Coordinator by writing to the (Administrator/Chief Executive Officer/Board of Directors/etc.) within 15 days of receiving the Section 1557 Coordinator's decision. The (Administrator/Chief Executive Officer/Board of Directors/etc.) shall issue a written decision in response to the appeal no later than 30 days after its filing.

The availability and use of this grievance procedure does not prevent a person from pursuing other legal or administrative remedies, including filing a complaint of discrimination on the basis of race, color, national origin, sex, age or disability in court or with the U.S. Department of Health and Human Services, Office for Civil Rights. A person can file a complaint of discrimination electronically through the Office for Civil Rights Complaint Portal, which is available at: *https://ocrportal.hhs.gov/ocr/portal/lobby.jsf,* or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201.

Complaint forms are available at: *http://www.hhs.gov/ocr/office/file/index.html.* Such complaints must be filed within 180 days of the date of the alleged discrimination.

[Name of covered entity] will make appropriate arrangements to ensure that individuals with disabilities and individuals with limited English proficiency are provided auxiliary aids and services or language assistance services, respectively, if needed to participate in this grievance process. Such arrangements may include, but are not limited to, providing qualified interpreters, providing taped cassettes of material for individuals with low vision, or assuring a barrier-free location for the proceedings. The Section 1557 Coordinator will be responsible for such arrangements.

Dated: May 11, 2016.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2016–11458 Filed 5–13–16; 11:15 am]

BILLING CODE 4153–01–P

FEDERAL REGISTER

Vol. 81 Wednesday,
No. 96 May 18, 2016

Part V

The President

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Proclamation 9446—National Defense Transportation Day and National Transportation Week, 2016
Proclamation 9447—National Hurricane Preparedness Week, 2016
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Presidential Documents

Title 3—

The President

Proclamation 9445 of May 13, 2016

Emergency Medical Services Week, 2016

By the President of the United States of America

A Proclamation

Every day across our Nation, women and men sacrifice precious time with their loved ones, working long and hard to provide emergency medical services (EMS) to people they have never met before. Often operating in the midst of trauma and heartbreak, these professionals deliver urgent and essential care, saving lives and upholding a timeless belief that defines who we are as Americans—that we all must look out for one another. This week, we recognize the daily heroism of our EMS professionals at all levels, and we express our gratitude for their efforts to keep us healthy and safe.

Embodying the grit, compassion, and courage that has driven our Nation forward since its founding, our emergency medical technicians, paramedics, 911 dispatchers, nurses, physicians, EMS medical directors, firefighters, and law enforcement officers reflect a spirit of selflessness that makes us all strive to live up to their example. Their families stand beside them, enduring extraordinary anticipation and exercising sincere patience each day. As the steady anchors in an otherwise unpredictable daily routine, these families offer unwavering support for EMS practitioners—giving them the support and strength necessary to fulfill the demands of their unending work.

EMS providers brave danger and uncertainty, and their efforts deserve our most profound appreciation. We rarely know when tragedy will strike, and in our most vulnerable moments, we rely on these dedicated professionals. During Emergency Medical Services Week, let us celebrate and support the EMS professionals who demonstrate the values at the heart of the American spirit, and let us thank them for their heroic work.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 15 through May 21, 2016, as Emergency Medical Services Week. I encourage all Americans to observe this occasion by showing their support for their local EMS providers and taking steps to improve their own personal safety and preparedness.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of May, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and fortieth.

[FR Doc. 2016–11922
Filed 5–17–16; 11:15 am]
Billing code 3295–F6–P

Presidential Documents

Proclamation 9446 of May 13, 2016

National Defense Transportation Day and National Transportation Week, 2016

By the President of the United States of America

A Proclamation

At the core of our national character is our persistent belief in what we, as a people, can accomplish as one. Connecting every corner of our country and each chapter of our Nation's story, our infrastructure has always played a critical role in helping us solve our shared challenges and in fueling the innovation and productivity that drive our economy. On National Defense Transportation Day and during National Transportation Week, we reflect on the importance of infrastructure throughout our history, and we recognize the need to invest in these essential pathways to our future.

From the National Road envisioned by our Founders to the Interstate Highway System first authorized six decades ago, the history of infrastructure projects in our country reflects the belief that the progress made by each generation is built on the efforts of those who came before. Our investments in transportation systems have not only driven extraordinary and innovative advances, but they have also uplifted our Nation in times of great trial. Authorizing the construction of hundreds of thousands of miles of roads, the Works Progress Administration—established by President Franklin D. Roosevelt—played a major role in lifting our Nation from the depths of the Great Depression. And America would not be what it is today without structures like the Golden Gate Bridge and the Hoover Dam—defining symbols of the daring ingenuity brought about by the grit and unwavering determination of our people.

In our time, it is imperative that we carry forward this legacy by rebuilding our roads, transit lines, bridges, ports, and water systems. That is why my Administration has worked to repair and modernize our transportation infrastructure; connected more individuals, businesses, and communities across our country to high-speed broadband; and called on the Congress to commit to making the long-term investments in our infrastructure on which our country depends. And because there is no greater threat to our planet and to future generations than the peril of a changing climate, I have put forward a plan for creating a 21st Century Clean Transportation System to put us on a course to develop secure, resilient infrastructure that can reduce carbon pollution while strengthening our economy.

Our transportation systems represent important parts of our history and heritage, but they are also critical to our safety and security, and ensuring they are stable and sound for future generations is vital. Our first responders travel our roads to confront danger and save lives; aid workers travel far and wide to bring relief in the wake of tragedy and devastation; and our Armed Forces utilize transportation networks each day to protect our Nation and our values.

This year, we mark 50 years since President Lyndon B. Johnson signed the Department of Transportation Act. Embodying both optimism for the future and a clear understanding of the work needed to shape that future, the founding of the Department of Transportation reminds us that America's progress has never been inevitable, that it has always depended on our people deciding, with boldness and vision, to renew our country's promise.

In that spirit, let us reaffirm our commitment to fulfilling this tremendous task in the face of the challenges and opportunities of today and tomorrow.

In recognition of the importance of our Nation's transportation infrastructure, and of the men and women who build, operate, maintain, and utilize it, the Congress has requested, by joint resolution approved May 16, 1957, as amended (36 U.S.C. 120), that the President designate the third Friday in May of each year as "National Defense Transportation Day," and, by joint resolution approved May 14, 1962, as amended (36 U.S.C. 133), that the week during which that Friday falls be designated as "National Transportation Week."

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, do hereby proclaim Friday, May 20, 2016, as National Defense Transportation Day and May 15 through May 21, 2016, as National Transportation Week. I call upon all Americans to recognize the importance of our Nation's transportation infrastructure and to acknowledge the contributions of those who build, operate, and maintain it.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of May, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and fortieth.

[FR Doc. 2016–11923
Filed 5–17–16; 11:15 am]
Billing code 3295–F6–P

Presidential Documents

Proclamation 9447 of May 13, 2016

National Hurricane Preparedness Week, 2016

By the President of the United States of America

A Proclamation

Each May, Americans set aside a week to raise awareness of the threat posed by hurricanes—storms that can devastate communities, neighborhoods, and local economies. The high winds, heavy rains, lightning, and tornadoes that can come with these powerful storms cause serious damage, but with proper preparation we can ensure the safety of ourselves and our loved ones. During National Hurricane Preparedness Week, we take deliberate action to safeguard our communities and work together to improve our resilience to hurricanes.

Our Nation is better prepared than ever before for today's storms. Our technology, forecasting, and models have improved, and we have new ways of disseminating vital warnings and storm-tracking information. Still, it is never too early to prepare for a potential disaster. I urge all Americans to visit www.Ready.gov and www.Hurricanes.gov/prepare to find key information on building an emergency supply kit and knowing what to do when disaster strikes. By having a plan ready, with ideas about how to respond to warnings, you can help avoid tragedy befalling you and your loved ones. Our communities are not resilient unless individuals have taken proper precautions.

Hurricane intensity and rainfall are projected to increase as a result of climate change. My Administration is dedicated to ensuring our resilience in response to these climate change-related impacts. We are working with the Congress, the private sector, and communities across America to build climate-resilient infrastructure, and we are cutting red tape to help those in need of recovery assistance better navigate the environmental reviews necessary to ensure a rapid and resilient recovery. The Federal Government is coordinating with State and local governments to ensure their climate action plans are up to date and to mitigate the worst effects of hurricanes—including through making buildings more resilient, home elevations, and improving drainage—so people are in a better position to avoid loss, damage, and interruption of critical services, and so our communities are in a better position to recover from storms. As a country, we continue to make strides in achieving the National Preparedness Goal of a secure and resilient Nation with the capabilities required across communities to prevent, protect against, mitigate, respond to, and recover from threats and hazards that pose the greatest risk.

This past summer, our Nation commemorated the 10th anniversary of Hurricane Katrina—a tragedy that claimed the lives of more than 1,800 of our fellow Americans. We all have a responsibility to step up and take action to protect our Nation from such devastating disasters. As we enter hurricane season, let us renew our commitment to that responsibility, and let us unite in common purpose to safeguard our communities.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 15 through May 21, 2016, as National Hurricane Preparedness Week. I call upon government agencies, private organizations, schools, media, and residents in the areas of our Nation vulnerable to hurricanes to share information about preparedness and response to help save lives and protect their communities.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of May, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and fortieth.

[FR Doc. 2016–11924
Filed 5–17–16; 11:15 am]
Billing code 3295–F6–P

Presidential Documents

Proclamation 9448 of May 13, 2016

Peace Officers Memorial Day and Police Week, 2016

By the President of the United States of America

A Proclamation

For generations, the brave women and men of our Nation's law enforcement have answered the call to serve and protect our communities. Enduring long shifts in dangerous and unpredictable circumstances, our Nation's peace officers embody the courage and honor that represent the best of America. On Peace Officers Memorial Day and during Police Week, we express our gratitude for the selfless public servants who wear the badge and put themselves in harm's way to keep us safe, and we pay respect for those who lost their lives in the line of duty.

In moments of danger and desperation, the first people we turn to are law enforcement officers. These often unsung heroes risk their lives and sacrifice precious time with loved ones so their fellow Americans can live in peace and security. But more than that, they are leaders in their communities, serving as mentors, coaches, friends, and neighbors—working tirelessly each day to ensure that the people they serve have the opportunities that should be afforded to all Americans. In honor of all they do, we must give these dedicated professionals the support and appreciation they deserve.

My Administration continues to work to ensure police departments and other law enforcement agencies throughout our country have the resources required to hire, train, and retain officers, provide officers with modern and necessary equipment, and utilize technology to enhance their communication networks. And our Federal law enforcement officers regularly partner with their State and local counterparts to address some of our Nation's most difficult problems. We know that strong community bonds are essential for law enforcement to do their jobs effectively. I established a Task Force on 21st Century Policing, bringing together law enforcement, academia, youth, civil rights, and community leaders to provide concrete recommendations to enhance public safety while building community trust. Law enforcement officials care deeply about their communities, and together with our partners in law enforcement, we must work to build up our neighborhoods, prevent crime before it happens, and put opportunity within reach for all our people.

Because each fallen peace officer is one too many, I proudly signed the Rafael Ramos and Wenjian Liu National Blue Alert Act last year—bipartisan legislation that establishes a national "Blue Alert" communications network to disseminate information about threats to officers. The legislation seeks to ensure that appropriate steps can be taken as quickly as possible to provide for an officer's safety. I also announced new, commonsense gun safety reforms to help keep guns out of the wrong hands and emphasized that the already dangerous job of an officer is far more dangerous than it should be because it remains too easy for criminals and people who are a danger to others or themselves to have access to guns.

It takes a special kind of courage to be a peace officer. Whether deputies or detectives, tribal police or forest service officers, beat cops or Federal agents, we hold up those who wear the badge as heroes. Though they too often spend their days witnessing America at its worst, in their extraordinary examples, we see America at its best. On this day and throughout this week, let us celebrate those who nobly serve each day—and remember those who made the ultimate sacrifice—to move our world toward a more just and safe tomorrow. May we carry forward their brave and selfless spirit as we keep working together to shape a future worthy of their commitment.

By a joint resolution approved October 1, 1962, as amended (76 Stat. 676), and by Public Law 103–322, as amended (36 U.S.C. 136–137), the President has been authorized and requested to designate May 15 of each year as "Peace Officers Memorial Day" and the week in which it falls as "Police Week."

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, do hereby proclaim May 15, 2016, as Peace Officers Memorial Day and May 15 through May 21, 2016, as Police Week. I call upon all Americans to observe these events with appropriate ceremonies and activities. I also call on the Governors of the United States and its Territories, and appropriate officials of all units of government, to direct that the flag be flown at half-staff on Peace Officers Memorial Day. I further encourage all Americans to display the flag at half-staff from their homes and businesses on that day.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of May, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and fortieth.

[FR Doc. 2016–11925
Filed 5–17–16; 11:15 am]
Billing code 3295–F6–P

Presidential Documents

Proclamation 9449 of May 13, 2016

World Trade Week, 2016

By the President of the United States of America

A Proclamation

The United States of America cannot afford to sit on the sidelines of the global economy. With over 95 percent of our Nation's potential customers living outside our borders, trade agreements are a vital part of our agenda for creating jobs and growing our economy—and smart trade agreements that level the playing field for American workers and businesses are a vital piece of middle-class economics. During World Trade Week, we reaffirm the importance of global trade, and we redouble our efforts to pursue trade deals that reflect American values and give our people a fair shot at success.

America's small businesses employ more than half of all Americans, and they represent 98 percent of our Nation's exporters. I am committed to a trade agenda that includes strong, enforceable provisions in our agreements that help our businesses—large and small—support higher-paying jobs and ship products stamped "Made in the USA" around the world. My Administration has ramped up enforcement of our trade laws like never before. Last year, I renewed and expanded the Trade Adjustment Assistance program, providing job training and other assistance to American workers. And earlier this year, I signed bipartisan legislation that helps us enforce our trade agreements—helping ensure that other countries play by the rules.

Some of our greatest economic opportunities abroad are in the Asia-Pacific region. For more than 5 years, the United States negotiated a new, forward-looking trade deal that puts workers first and ensures we write the rules of the road for trade in the 21st century. The Trans-Pacific Partnership (TPP) brings 12 countries representing nearly 40 percent of the global economy together to trade and invest in the Asia-Pacific—one of the world's fastest growing regions. The TPP includes fully enforceable provisions that ensure a free and open Internet, respect intellectual property rights, protect the environment, and uphold worker rights. It eliminates more than 18,000 taxes imposed by other countries on American products, and it bolsters our leadership abroad while supporting good jobs here at home. The United States signed TPP this year, and I will continue working with the Congress to enact it as soon as possible.

The largest trade and investment relationship in the world is between the United States and the European Union—yet too many barriers remain in the way of even greater trade and investment between us. That is why, together, we have moved forward with the Trans-Atlantic Trade and Investment Partnership (T–TIP), which will eliminate tariffs, simplify procedures, bridge differences in regulations, and cut red tape. T–TIP also enforces strong standards, and it will reinforce our larger trans-Atlantic relationship—the foundation of our prosperity and security since World War II.

Our global economy's growth is fueled by trade. While understandable skepticism exists about trade, particularly in places that have been hit hard by trade deals of the past, we cannot ignore the realities of the new economy. Rather, we must set the highest standards for our trade agreements, enforce the commitments and obligations of our trading partners, and help write the rules of the road for trade in the 21st-century global economy, as we have done with TPP and will do through T–TIP. And we must continue to harness the dynamism and entrepreneurship inherent to who we are as a people and enable Americans to sell the best products and ideas in the world to every corner of the world. This week, let us renew our commitment to that mission and work together toward a future of greater opportunity for all.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 15 through May 21, 2016, as World Trade Week. I encourage all Americans to visit www.WhiteHouse.gov/Trade and to observe this week with events, trade shows, and educational programs that celebrate and inform Americans about the benefits of trade to our Nation and the global economy.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of May, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and fortieth.

[FR Doc. 2016–11926
Filed 5–17–16; 11:15 am]
Billing code 3295–F6–P

Presidential Documents

Notice of May 17, 2016

Continuation of the National Emergency With Respect to Burma

On May 20, 1997, the President issued Executive Order 13047, certifying to the Congress under section 570(b) of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1997 (Public Law 104–208), that the Government of Burma had committed large-scale repression of the democratic opposition in Burma after September 30, 1996, thereby invoking the prohibition on new investment in Burma by United States persons contained in that section. The President also declared a national emergency pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701–1706, to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the actions and policies of the Government of Burma.

The actions and policies of the Government of Burma continue to pose an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared on May 20, 1997, and the measures adopted to deal with that emergency in Executive Orders 13047 of May 20, 1997; 13310 of July 28, 2003; 13448 of October 18, 2007; 13464 of April 30, 2008; 13619 of July 11, 2012; and 13651 of August 6, 2013, must continue in effect beyond May 20, 2016. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to Burma declared in Executive Order 13047. This notice shall be published in the *Federal Register* and transmitted to the Congress.

THE WHITE HOUSE,
May 17, 2016.

[FR Doc. 2016–11936
Filed 5–17–16; 11:15 am]
Billing code 3295–F6–P

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